

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMO DEVELOPMENT, LLC, AMO
MANUFACTURING USA, LLC and
AMO SALES AND SERVICE, INC.,

Plaintiffs,

v.

ALCON VISION, LLC,
ALCON LABORATORIES, INC. and
ALCON RESEARCH, LLC,

Defendants.

ALCON INC., ALCON RESEARCH,
LLC, and ALCON VISION, LLC,

Plaintiffs,

v.

AMO DEVELOPMENT, LLC,
AMO MANUFACTURING USA, LLC,
AMO SALES AND SERVICE, INC.,
and JOHNSON & JOHNSON
SURGICAL VISION, INC.,

Defendants.

Redacted - Public Version

C.A. No. 20-842-CFC-JLH



JURY TRIAL DEMANDED

**FIRST AMENDED ANSWER TO SECOND AMENDED COMPLAINT AND
COUNTERCLAIMS**

Unable to compete in the marketplace, Plaintiffs AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc. (collectively, “AMO”) filed this suit, seeking to enjoin Defendants Alcon Vision, LLC, Alcon Laboratories, Inc. and Alcon Research, LLC (collectively, “Alcon” or “Defendants”) from selling its LenSx® Laser System, the device that literally created the market Plaintiffs now attempt to compete in. Rather than innovating, AMO has been using Alcon’s patented LenSx® technology to try to compete with Alcon. Frustrated that Alcon and its predecessors were the innovators and leaders in this space, AMO spent years developing a smoke screen, filing dozens of patent applications seeking to claim the very concept of femtosecond laser-assisted cataract surgery (“FLACS”), a concept invented by others and reduced to practice commercially in Alcon’s LenSx® product long before AMO. This lawsuit is AMO’s brazen attempt to use that smoke screen to block Alcon from selling its patented LenSx® product. When the smoke clears, this lawsuit—including Alcon’s affirmative counterclaims—will reveal that Alcon is the innovator and AMO has been infringing Alcon’s patented LenSx® technology.

ANSWER

Defendants now demand a trial by jury on all issues so triable and answer the Second Amended Complaint of Plaintiffs and state their affirmative defenses and counterclaims against AMO as follows:

NATURE OF THE ACTION¹

1. Defendants admit that Plaintiffs have brought an action for patent infringement of the Asserted Patents. Defendants deny all remaining allegations of paragraph 1.
2. Defendants admit that Plaintiffs have brought an action for copyright infringement. Defendants deny all remaining allegations of paragraph 2.

PARTIES

3. Upon information and belief, admitted.
4. Upon information and belief, admitted.
5. Upon information and belief, admitted.
6. Admitted.
7. Admitted.
8. Admitted.

JURISDICTION AND VENUE

9. Defendants admit that Plaintiffs have brought an action under the patent laws of the United States, Title 35 of the United States Code, and copyright laws of the United States, Title 17 of the United States Code, but deny that Defendants have committed or are committing acts of patent or copyright infringement. Defendants

¹ The headings in the amended complaint are reproduced herein for the convenience of the reader. To the extent such headings include or infer allegations, they are denied.

admit that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Alcon Vision admits it is a Delaware limited liability company and that, for purposes of this action only, this Court has personal jurisdiction over it. Alcon Vision denies all remaining allegations of paragraph 10, including that it has committed the complained-of acts of patent and copyright infringement in Delaware.

11. Alcon Laboratories admits it is a Delaware corporation and that, for purposes of this action only, this Court has personal jurisdiction over it. Alcon Laboratories denies all remaining allegations of paragraph 11, including that it has committed the complained-of acts of patent and copyright infringement in Delaware.

12. Alcon Research admits it is a Delaware limited liability company and that, for purposes of this action only, this Court has personal jurisdiction over it. Alcon Research denies all remaining allegations of paragraph 12, including that it has committed the complained-of acts of patent and copyright infringement in Delaware.

13. Admitted.

BACKGROUND

14. Defendants admit the title on the face of the '084 patent is "Apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '084 patent appears on its face to have

issued on March 12, 2013. Defendants admit a copy that appears to be the '084 patent is attached to Plaintiffs' Complaint as Exhibit A. Defendants deny the remaining allegations of paragraph 14.

15. Defendants admit the title on the face of the '921 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '921 patent appears on its face to have issued on March 26, 2013. Defendants admit a copy that appears to be the '921 patent is attached to Plaintiffs' Complaint as Exhibit B. Defendants deny the remaining allegations of paragraph 15.

16. Defendants admit the title on the face of the '497 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '497 patent appears on its face to have issued on April 23, 2013. Defendants admit a copy that appears to be the '497 patent is attached to Plaintiffs' Complaint as Exhibit C. Defendants deny the remaining allegations of paragraph 16.

17. Defendants admit the title on the face of the '724 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '724 patent appears on its face to have issued on August 6, 2013. Defendants admit a copy that appears to be the '724

patent is attached to Plaintiffs' Complaint as Exhibit D. Defendants deny the remaining allegations of paragraph 17.

18. Defendants admit the title on the face of the '001 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '001 patent appears on its face to have issued on April 29, 2014. Defendants admit a copy that appears to be the '001 patent is attached to Plaintiffs' Complaint as Exhibit E. Defendants deny the remaining allegations of paragraph 18.

19. Defendants admit the title on the face of the '415 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '415 patent appears on its face to have issued on August 4, 2015. Defendants admit a copy that appears to be the '415 patent is attached to Plaintiffs' Complaint as Exhibit F. Defendants deny the remaining allegations of paragraph 19.

20. Defendants admit the title on the face of the '448 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '448 patent appears on its face to have issued on August 11, 2015. Defendants admit a copy that appears to be the '448 patent is attached to Plaintiffs' Complaint as Exhibit G. Defendants deny the remaining allegations of paragraph 20.

21. Defendants admit the title on the face of the '732 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '732 patent appears on its face to have issued on August 18, 2015. Defendants admit a copy that appears to be the '732 patent is attached to Plaintiffs' Complaint as Exhibit H. Defendants deny the remaining allegations of paragraph 21.

22. Defendants admit the title on the face of the '725 patent is "Method and apparatus for patterned plasma-mediated laser trephination of the lens capsule and three dimensional phaco-segmentation," and the '725 patent appears on its face to have issued on September 8, 2015. Defendants admit a copy that appears to be the '725 patent is attached to Plaintiffs' Complaint as Exhibit I. Defendants deny the remaining allegations of paragraph 22.

23. Defendants admit the title on the face of the '023 patent is "Method and apparatus for creating ocular surgical and relaxing incisions," and the '023 patent appears on its face to have issued on January 12, 2016. Defendants admit a copy that appears to be the '023 patent is attached to Plaintiffs' Complaint as Exhibit J. Defendants deny the remaining allegations of paragraph 23.

24. Defendants admit the title on the face of the '024 patent is "Method and apparatus for creating ocular surgical and relaxing incisions," and the '024 patent appears on its face to have issued on January 12, 2016. Defendants admit a copy

that appears to be the '024 patent is attached to Plaintiffs' Complaint as Exhibit K.

Defendants deny the remaining allegations of paragraph 24.

25. Defendants admit the title on the face of the '648 patent is "Apparatus for patterned plasma-mediated laser ophthalmic surgery," and the '648 patent appears on its face to have issued on October 25, 2016. Defendants admit a copy that appears to be the '648 patent is attached to Plaintiffs' Complaint as Exhibit L.

Defendants deny the remaining allegations of paragraph 25.

26. Defendants admit the title on the face of the '903 patent is "Apparatus for patterned plasma-mediated laser ophthalmic surgery," and the '903 patent appears on its face to have issued on July 4, 2017. Defendants admit a copy that appears to be the '903 patent is attached to Plaintiffs' Complaint as Exhibit M.

Defendants deny the remaining allegations of paragraph 26.

27. Defendants admit the title on the face of the '904 patent is "Apparatus for patterned plasma-mediated laser ophthalmic surgery," and the '904 patent appears on its face to have issued on July 4, 2017. Defendants admit a copy that appears to be the '904 patent is attached to Plaintiffs' Complaint as Exhibit N.

Defendants deny the remaining allegations of paragraph 27.

28. Defendants admit the title on the face of the '356 patent is "Method and apparatus for creating ocular surgical and relaxing incisions," and the '356 patent appears on its face to have issued on August 13, 2019. Defendants admit a copy that

appears to be the '356 patent is attached to Plaintiffs' Complaint as Exhibit O. Defendants deny the remaining allegations of paragraph 28.

29. Defendants admit the title on the face of the '548 patent is "Method and apparatus for creating ocular surgical and relaxing incisions," and the '548 patent appears on its face to have issued on July 14, 2020. Defendants admit a copy that appears to be the '548 patent is attached to Plaintiffs' Complaint as Exhibit P. Defendants deny the remaining allegations of paragraph 29.

30. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 30 and therefore deny them.

31. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 31 and therefore deny them.

32. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 32 and therefore deny them.

33. Defendants admit that the certificate of registration attached to Plaintiffs' Second Amended Complaint as Exhibit Q lists its copyright registration number as TX0008892568 and its "Title of Work" as "IntraLase FS Model 2/Model 3 Software." Defendants deny the remaining allegations of paragraph 33.

34. Defendants admit that the certificate of registration attached to Plaintiffs' Second Amended Complaint as Exhibit R lists its copyright registration number as TX0008892570 and its "Title of Work" as "IntraLase FS Model 2/Model

3 Software Version 1.01.” Defendants deny the remaining allegations of paragraph
34.

35. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit S lists its copyright registration number as TX0008892579 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.02.” Defendants deny the remaining allegations of paragraph
35.

36. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit T lists its copyright registration number as TX0008892616 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.03.” Defendants deny the remaining allegations of paragraph
36.

37. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit U lists its copyright registration number as TX0008892571 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.04.” Defendants deny the remaining allegations of paragraph
37.

38. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit V lists its copyright registration number as TX0008892576 and its “Title of Work” as “IntraLase FS Model 2/Model

3 Software Version 1.05.” Defendants deny the remaining allegations of paragraph
38.

39. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit W lists its copyright registration number as TX0008892583 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.06.” Defendants deny the remaining allegations of paragraph 39.

40. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit X lists its copyright registration number as TX0008892582 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.07.” Defendants deny the remaining allegations of paragraph 40.

41. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit Y lists its copyright registration number as TX0008892586 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.08.” Defendants deny the remaining allegations of paragraph 41.

42. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit Z lists its copyright registration number as TX0008892565 and its “Title of Work” as “IntraLase FS Model 2/Model

3 Software Version 1.10.” Defendants deny the remaining allegations of paragraph 42.

43. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit AA lists its copyright registration number as TX0008892585 and its “Title of Work” as “IntraLase FS Model 2/Model 3 Software Version 1.12.” Defendants deny the remaining allegations of paragraph 43.

44. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit BB lists its copyright registration number as TX0008892564 and its “Title of Work” as “iFS Advanced Femtosecond Laser Software Version 2.02.” Defendants deny the remaining allegations of paragraph 44.

45. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit CC lists its copyright registration number as TX0008892567 and its “Title of Work” as “iFS Advanced Femtosecond Laser Software Version 2.04.” Defendants deny the remaining allegations of paragraph 45.

46. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit DD lists its copyright registration number as TX0008892618 and its “Title of Work” as “iFS Advanced Femtosecond

Laser Software Version 2.20.” Defendants deny the remaining allegations of paragraph 46.

47. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit EE lists its copyright registration number as TX0008892614 and its “Title of Work” as “iFS Advanced Femtosecond Laser Software Version 2.30.” Defendants deny the remaining allegations of paragraph 47.

48. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit FF lists its copyright registration number as TX0008892580 and its “Title of Work” as “iFS Advanced Femtosecond Laser Software Version 2.50.” Defendants deny the remaining allegations of paragraph 48.

49. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit GG lists its copyright registration number as TX0008892621 and its “Title of Work” as “iFS Advanced Femtosecond Laser Software Version 2.60.” Defendants deny the remaining allegations of paragraph 49.

50. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit HH lists its copyright registration number as TX0008892612 and its “Title of Work” as “iFS Advanced Femtosecond

Laser Software Version 2.70.” Defendants deny the remaining allegations of paragraph 50.

51. Plaintiffs’ Second Amended Complaint does not contain an Exhibit II and thus Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 51 and therefore deny them.

52. Plaintiffs’ Second Amended Complaint does not contain an Exhibit JJ and thus Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 52 and therefore deny them.

53. Defendants admit that the certificate of registration attached to Plaintiffs’ Second Amended Complaint as Exhibit KK lists its copyright registration number as TX0008971676 and its “Title of Work” as “IntraLase FS Laser Operator’s Manual.” Defendants deny the remaining allegations of paragraph 53.

54. Defendants admit that the “Registration Decision Date” on the copyright registrations in Exhibits Q–HH is prior to the filing date of Plaintiffs’ First Amended Complaint. Defendants admit that the “Registration Decision Date” on the copyright registration in Exhibit KK is prior to the filing of Plaintiffs’ Second Amended Complaint. Defendants deny the remaining allegations of paragraph 54.

55. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 55 and therefore deny them.

56. Admitted.

57. Admitted.

58. Admitted.

59. Denied.

60. Defendants admit that, generally, the Asserted Patents address cataract surgery. Defendants deny the remaining allegations of paragraph 60.

61. Defendants lack knowledge or information sufficient to form a belief about the truth of Plaintiffs' allegations regarding the laser and therefore deny them. Defendants deny the remaining allegations of paragraph 61.

62. Defendants admit that the inventors of the Asserted Patents are authors on the article "Femtosecond Laser-Assisted Cataract Surgery with Integrated Optical Coherence Tomography," published in November 2010 in *Science Translation Medicine*. Defendants admit that the above image appears in that article. Defendants deny the remaining allegations of paragraph 62.

63. Defendants admit that the above image appears in the aforementioned *Science Translational Medicine* article. Defendants deny the remaining allegations of paragraph 63.

64. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

65. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

66. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

67. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

68. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

69. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

70. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

71. Denied.

72. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

73. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

74. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

75. Denied.

76. Defendants admit Alcon Research manufactures and Alcon Vision markets LenSx® in the United States. Defendants admit LenSx® is an OCT-guided

laser system to assist the surgeon in identifying targets. Defendants admit LenSx® is designed and intended to perform anterior capsulotomy, lens fragmentation, and corneal primary, secondary, and arcuate incisions, among other procedures. Defendants deny the remaining allegations of paragraph 76.

77. Defendants admit Alcon Vision's customers in the United States have used LenSx®. For the remaining allegations of paragraph 77, Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

78. Defendants admit that LenSx® and Catalys are among the competing femtosecond laser surgical systems. Defendants deny the remaining allegations of paragraph 78.

79. Defendants admit Alcon Research manufactures LenSx® in the United States. Defendants admit that LenSx® is distributed both domestically and internationally. Defendants admit that Alcon Research authored at least portions of at least one version of the LenSx® Operator's Manual, which instructs surgeons how to use LenSx® to perform anterior capsulotomy, lens fragmentation, and corneal primary, secondary, and arcuate incisions, among other procedures. Defendants deny the remaining allegations of paragraph 79.

80. Defendants admit that Alcon Vision offers to sell and sells LenSx® in the United States and is responsible for repair and maintenance of certain LenSx® systems. Defendants deny the remaining allegations of paragraph 80.

81. Denied.

82. Denied.

83. Defendants admit LenSx Lasers, Inc. was founded in 2008 and originally developed the LenSx®. Defendants admit that OptiMedica filed the provisional application to which the Palanker Patents attempt to claim priority on January 10, 2005. For the remaining allegations of paragraph 83, Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

84. Defendants admit that an Alcon affiliate acquired LenSx Lasers, Inc. in July 2010, and LenSx Lasers, Inc. was renamed “Alcon LenSx, Inc.” in September 2010. Defendants admit that Alcon LenSx, Inc. merged with and into Alcon Research, LLC in April 2021. Defendants admit Alcon LenSx, Inc. launched LenSx® in the United States in 2011. Defendants admit that they respect the intellectual property of others in technological fields where Defendants are operating. Defendants deny the remaining allegations in paragraph 84.

85. Defendants admit that WO 2006/074469 published on July 13, 2006, and claims priority to the application that resulted in the '084 patent. Defendants

admit that WO 2006/075569 is cited on the face of certain Alcon LenSx patents, but deny that this demonstrates knowledge. Defendants deny the remaining allegations of paragraph 85.

86. Defendants admit that US 2006/0195076 published on August 31, 2006, and is the U.S. application that resulted in the '084 patent. Defendants admit that US 2006/0195076 is cited on the face of certain Alcon LenSx patents, but deny that this demonstrates knowledge. Defendants deny the remaining allegations of paragraph 86.

87. Defendants admit that US 2008/0281303 published on November 13, 2008, and is the U.S. application that resulted in the '023 patent. Defendants admit that US 2008/0281303 is cited on the face of certain Alcon LenSx patents, but deny that this demonstrates knowledge. Defendants deny the remaining allegations of paragraph 87.

88. Defendants admit an Alcon affiliate acquired LenSx Lasers Inc. in July 2010. Defendants admit the acquisition agreement includes an Escrow Balance. Defendants deny the remaining allegations in paragraph 88.

89. Defendants admit "Femtosecond Laser-Assisted Cataract Surgery with Integrated Optical Coherence Tomography" was published in the November 2010 issue of *Science Translational Medicine* and is accurately quoted. Defendants admit

the *Science Translational Medicine* article listed patent applications that resulted in the '084 patent. Defendants deny the remaining allegations of paragraph 89.

90. Defendants admit "The Origins of Laser Cataract Surgery" appears to be published in a March 2011 article published in *Cataract & Refractive Surgery Today* and appears to be accurately quoted. Defendants deny the remaining allegations of paragraph 90.

91. Defendants admit that a press release which appears to have been released on February 25, 2013 is accurately quoted and indicated that the '084 patent would issue on March 12, 2013. Defendants admit that one or more Alcon entities were aware of this press release by March 12, 2013.

92. Defendants admit one or more Alcon entities became aware of the '084 patent by March 12, 2013. Defendants admit that U.S. Patent No. 8,394,084 is cited on the face of certain Alcon LenSx patents, but deny that this demonstrates knowledge. Defendants admit that one or more Alcon entities became aware of the '497 patent by April 29, 2013. Defendants admit that one or more Alcon entities became aware of the '921 patent by June 3, 2013. Defendants admit that one or more Alcon entities became aware of the '724 patent by August 12, 2013. Defendants admit that one or more Alcon entities became aware of the '001 patent by May 6, 2014. Defendants deny the remaining allegations of paragraph 92.

93. Defendants admit that J&J Vision identified the Palanker Patents on March 24, 2020 and Defendants became aware of the Palanker Patents by that date. Defendants admit that J&J Vision provided a cursory claim chart for claim 1 of the '084 patent on April 14, 2020, but deny that J&J Vision provided any other claim charts for the Palanker Patents. Defendants deny the remaining allegations in paragraph 93.

94. Defendants admit that J&J Vision identified the Culbertson Patents on July 14, 2020 and Defendants became aware of the Culbertson Patents by that date. Defendants admit that J&J Vision provided cursory claim charts for claim 1 of each of the Culbertson Patents on August 4, 2020, but deny that J&J Vision provided any other claim charts for the Culbertson Patents. Defendants deny the remaining allegations in paragraph 94.

95. Denied.

96. Defendants deny that the patented technology was fundamental to the operation and success of the LenSx® and further deny knowledge of this alleged fact. After a reasonable investigation, Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 96 and therefore deny them.

97. Denied.

98. Denied.

99. Defendants admit that Dr. Ron Kurtz founded LenSx Lasers, Inc. and that Dr. Tibor Juhasz, Peter Goldstein, and Kostadin Vardin are all former employees of LenSx Lasers, Inc. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 99 and therefore deny them.

100. Denied.

101. Defendants admit that LenSx® received clearance from the FDA for anterior capsulotomies in August 2009, and FDA clearance for corneal incisions in December 2009. Defendants deny the remaining allegations of paragraph 101.

102. Defendants deny that they unlawfully used and are continuing to use J&J Vision's copyrighted computer programs and that the LenSx® software exhibits an overwhelming number of telltale signs of copying of J&J Vision's copyrighted computer programs. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 102 and therefore deny them.

103. Defendants admit that they have made at least three submissions to the FDA, known as 510(k) filings, since 2014 seeking approval to market modified versions of LenSx® under "substantial equivalence." Defendants admit that the 2016 510(k) filing disclosed a modification to "implement the use of a planner Ethernet device for cataract surgery, re-enabling flap functionality that was

previously cleared, and introducing an optional lens fragmentation pattern whose parameters are within previously cleared treatment ranges.” Defendants admit that the 2017 510(k) filing indicated that there were no changes to the LenSx® software. Defendants admit that the 2018 510(k) filing indicated that software updates were implemented to support new functionality. Defendants deny the remaining allegations of paragraph 103.

104. Defendants admit that Plaintiffs identified certain alleged similarities between the iFS® Laser and the LenSx® software on July 14, 2020, but Plaintiffs did not give Defendants access to the iFS® source code so that the alleged similarities could be analyzed. Defendants deny the remaining allegations of paragraph 104.

105. Defendants admit that the parties exchanged source code in late 2020 and that the iFS® Laser and the LenSx® source code contained a number of overlapping lines of code. Defendants admit that Alcon continues to manufacture and sell LenSx® and further state that the Court did not grant J&J Vision’s motion for a preliminary injunction at least in part because it did not show irreparable harm. Defendants deny the remaining allegations of paragraph 105.

106. Defendants admit that they manufacture LenSx® in the United States and that LenSx® software has been updated. Defendants deny the remaining allegations of paragraph 106.

107. Defendants admit that they have updated LenSx® software.

Defendants deny the remaining allegations of paragraph 107.

108. Defendants admit that they have distributed LenSx® within the United States and that LenSx® software has been updated. Defendants deny the remaining allegations of paragraph 108.

109. Defendants admit that they export LenSx®, which includes LenSx® software. Defendants deny the remaining allegations of paragraph 109.

110. Defendants admit that copies of LenSx® software are made each time software is loaded into the random access memory of a LenSx® device, but deny that constitutes creating unauthorized copies of protected elements of J&J Vision's alleged copyrighted computer programs. Defendants deny the remaining allegations of paragraph 110.

111. Defendants admit that Plaintiffs identified certain alleged similarities between the iFS® Laser and the LenSx® software on July 14, 2020 and threatened a suit for copyright infringement. Defendants deny that the July 14, 2020 letter from Plaintiffs provided evidence of copying. Defendants deny the remaining allegations of paragraph 111.

112. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

113. Defendants admit that ALCON_LENSX044001 is titled “Software Architecture Description” and Plaintiffs identified portions of JJSV_0133829 which they claim were copied. Defendants admit that certain LenSx documents contain the term “IntraLase,” but deny that this demonstrates that those documents originated at IntraLase. Defendants deny the remaining allegations of paragraph 113.

114. Defendants admits that Alcon submitted a 510(k) for LenSx® in 2017. For the remaining allegations of paragraph 114, Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

115. Defendants admit that Alcon provides the LenSx® operator’s manual to its customers. For the remaining allegations of paragraph 115, Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

116. Denied.

117. Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

COUNT I²

Infringement of the '084 Patent

118. Defendants incorporate by reference their answers to paragraphs 1 through 117 as if fully set forth herein.

119. Denied.

120. Denied.

121. Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 121.

122. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;" "[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the

² Defendants have moved to dismiss certain allegations contained herein. Nevertheless, Defendants are providing answers to those allegations. Defendants' answers are not intended to and do not act as a waiver of Defendants' arguments regarding the deficiencies of those allegations, as set forth in the motion to dismiss.

focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 122.

123. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 123.

124. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 124.

125. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 125.

126. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the LenSx® displays a 2D representation of the anterior and posterior surfaces of the lens capsule and indicates the depth of the anterior capsule. Defendants deny the remaining allegations of paragraph 126.

127. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 127.

128. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision" and "[t]he location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location." Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for

lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants admit LenSx® has a 50 kHz repetition rate and maximum pulse energy of 15 microjoules for cataract surgery. Defendants deny the remaining allegations of paragraph 128.

129. Denied.

130. Denied.

131. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 131.

132. Denied.

133. Denied.

134. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile

disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 134.

135. Denied.

136. Defendants admit they are not expressly licensed under the ’084 patent, but deny that Defendants need a license to that patent.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

COUNT II

Infringement of the ’921 Patent

141. Defendants incorporate by reference their answers to paragraphs 1 through 140 as if fully set forth herein.

142. Denied.

143. Denied.

144. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for

lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 144.

145. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;" "[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;" and a "computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision." Defendants admit that the LenSx® achieves photodisruption through dielectric breakdown within the tissue structures. Defendants deny the remaining allegations of paragraph 145.

146. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 146.

147. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "The LenSx® Laser System uses

focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 147.

148. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 148.

149. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 149.

150. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit that a completed anterior capsulotomy transects the anterior capsule. Defendants deny the remaining allegations of paragraph 150.

151. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 151.

152. Denied.

153. Denied.

154. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “LenSx® Laser requires use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 154.

155. Denied.

156. Denied.

157. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 157.

158. Denied.

159. Defendants admit they are not expressly licensed under the '921 patent, but deny that Defendants need a license to that patent.

160. Denied.

161. Denied.

162. Denied.

163. Denied.

COUNT III

Infringement of the '497 Patent

164. Defendants incorporate by reference their answers to paragraphs 1 through 163 as if fully set forth herein.

165. Denied.

166. Denied.

167. Defendants admit that LenSx® is capable of making incisions in the eye during cataract surgery. Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients

undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 167.

168. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 168.

169. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit the cited image appears to be an image of the LenSx® user interface. For the remaining allegations of paragraph 169, Defendants lack knowledge or information sufficient to form a belief about the truth of these allegations and therefore deny them.

170. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea"; "a computer monitors and controls the beam energy, repetition rate, safety shutters, footswitch, laser diagnostics, the position of the scanners and the position of the scanning objective lens"; "[t]he Lens

Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or Frag. Chop and Cylinder patterns may be combined,” and “[l]ens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule.” Defendants admit LenSx® may be used to perform phacofragmentation of the crystalline lens. Defendants deny the remaining allegations of paragraph 170.

171. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 171.

172. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 172.

173. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 173.

174. Denied.

175. Denied.

176. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products

constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 176.

177. Denied.

178. Denied.

179. Defendants admit they are not expressly licensed under the ’497 patent, but deny that Defendants need a license to that patent.

180. Denied.

181. Denied.

182. Denied.

COUNT IV

Infringement of the ’724 Patent

183. Defendants incorporate by reference their answers to paragraphs 1 through 182 as if fully set forth herein.

184. Denied.

185. Denied.

186. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx®

Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants admit that the LenSx® laser pulses are directed in a manner to avoid damage to the retina of the eye. Defendants deny the remaining allegations of paragraph 186.

187. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 187.

188. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 188.

189. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® uses a computer-controlled scanning system. Defendants deny the remaining allegations of paragraph 189.

190. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “[t]he treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete, followed by

successive x-shaped scans created a few microns apart. As each scan is completed, the lateral extent of the scans is adjusted to fill-in the elliptically shaped volume. The result is two or more vertically oriented, elliptically shaped planes that intersect at the lens center. As an alternative, a number of cylindrical shells may be generated in lieu of the planes or in combination with the planes. The pattern is automatically completed when the programmed anterior depth is reached.” Defendants admit LenSx® may be used to perform phacofragmentation of the crystalline lens. Defendants deny the remaining allegations of paragraph 190.

191. Denied.

192. Denied.

193. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 193.

194. Denied.

195. Denied.

196. Defendants admit they are not expressly licensed under the '724 patent, but deny that Defendants need a license to that patent.

197. Denied.

198. Denied.

199. Denied.

COUNT V

Infringement of the '001 Patent

200. Defendants incorporate by reference their answers to paragraphs 1 through 199 as if fully set forth herein.

201. Denied.

202. Denied.

203. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants deny the remaining allegations of paragraph 203.

204. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials

have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 204.

205. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit that a completed anterior capsulotomy transects the anterior capsule. Defendants deny the remaining allegations of paragraph 205.

206. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;" "a computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.... The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location," "[t]he treatment pattern begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached," "[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens. The anterior capsulotomy is created by scanning a cylindrical shell." Defendants deny the remaining allegations of paragraph 206.

207. Denied.

208. Denied.

209. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 209.

210. Denied.

211. Denied.

212. Defendants admit they are not expressly licensed under the ’001 patent, but deny that Defendants need a license to that patent.

213. Denied.

214. Denied.

215. Denied.

216. Denied.

COUNT VI

Infringement of the '415 Patent

217. Defendants incorporate by reference their answers to paragraphs 1 through 216 as if fully set forth herein.

218. Denied.

219. Denied.

220. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 220.

221. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials

have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 221.

222. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 222.

223. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: “[c]onsistent with well-established femtosecond laser principles, the laser engine uses a conventional amplified laser design in which pulses with sufficient bandwidth are generated by an oscillator, amplified to higher energies, and finally compressed in time to femtosecond pulse duration;” and “[t]he beam of compressed pulses from the laser then enters the energy monitoring assembly.” Defendants deny the remaining allegations of paragraph 223.

224. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: “[t]he LenSx® Laser System uses focused femtosecond laser pulses;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” “[t]he location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location;” “[c]ircle scan OCT image of the

lens and capsule is displayed [on] the top right area of the Surgical Display. The circle scan is performed along the Capsule Pattern diameter as defined on the video microscope image of the eye;” “[t]he Capsule Pattern is used to perform an anterior capsulotomy of the crystalline lens;” “[a]nterior capsulotomy patterns are programmed to cut from at least 100 microns below to 100 microns above the anterior capsule;” “[t]he treatment pattern begins as a scanned circle located below the depth of the anterior capsule. Once a scanned circle is completed, a new circle is scanned a few microns above the first circle. As each circle is completed, a cylindrical incision is created. The pattern is automatically completed when the anterior extent of the incision is reached.” Defendants deny the remaining allegations of paragraph 224.

225. Denied.

226. Denied.

227. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 227.

228. Denied.

229. Denied.

230. Defendants admit they are not expressly licensed under the '415 patent, but deny that Defendants need a license to that patent.

231. Denied.

232. Denied.

233. Denied.

COUNT VII

Infringement of the '448 Patent

234. Defendants incorporate by reference their answers to paragraphs 1 through 233 as if fully set forth herein.

235. Denied.

236. Denied.

237. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale

precision.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 237.

238. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “houses the laser source, power supplies, control electronics, cooling system, beam delivery device, optical coherence tomography (OCT) device, video microscope and computers;” “[t]he LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[a] computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 238.

239. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials

have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 239.

240. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 240.

241. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 241.

242. Denied.

243. Denied.

244. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 244.

245. Denied.

246. Denied.

247. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 247.

248. Denied.

249. Defendants admit they are not expressly licensed under the ’448 patent, but deny that Defendants need a license to that patent.

250. Denied.

251. Denied.

252. Denied.

253. Denied.

COUNT VIII

Infringement of the ’732 Patent

254. Defendants incorporate by reference their answers to paragraphs 1 through 253 as if fully set forth herein.

255. Denied.

256. Denied.

257. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants deny the remaining allegations of paragraph 257.

258. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 258.

259. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 259.

260. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 260.

261. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 261.

262. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 262.

263. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 263.

264. Denied.

265. Denied.

266. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be

observed,” but deny that the quotations are evidence of inducing infringement.

Defendants deny the remaining allegations of paragraph 266.

267. Denied.

268. Denied.

269. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 269.

270. Denied.

271. Defendants admit they are not expressly licensed under the ’732 patent, but deny that Defendants need a license to that patent.

272. Denied.

273. Denied.

274. Denied.

275. Denied.

COUNT IX

Infringement of the '725 Patent

276. Defendants incorporate by reference their answers to paragraphs 1 through 275 as if fully set forth herein.

277. Denied.

278. Denied.

279. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants deny the remaining allegations of paragraph 279.

280. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 280.

281. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan, but does not acquire point by point image data. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 281.

282. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants admit that a computer monitors and controls the beam, the position of the scanners and the position of the scanning objective lens. Defendants deny the remaining allegations of paragraph 282.

283. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 283.

284. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 284.

285. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 285.

286. Denied.

287. Denied.

288. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 288.

289. Denied.

290. Denied.

291. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 291.

292. Denied.

293. Defendants admit they are not expressly licensed under the '725 patent, but deny that Defendants need a license to that patent.

294. Denied.

295. Denied.

296. Denied.

297. Denied.

COUNT X

Infringement of the '023 Patent

298. Defendants incorporate by reference their answers to paragraphs 1 through 297 as if fully set forth herein.

299. Denied.

300. Denied.

301. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 301.

302. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 302.

303. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 303.

304. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 304.

305. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 305.

306. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 306.

307. Denied.

308. Denied.

309. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be

observed,” but deny that the quotations are evidence of inducing infringement.

Defendants deny the remaining allegations of paragraph 309.

310. Denied.

311. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 311.

312. Defendants admit they are not expressly licensed under the ’023 patent, but deny that Defendants need a license to that patent.

313. Denied.

314. Denied.

315. Denied.

316. Denied.

COUNT XI

Infringement of the ’024 Patent

317. Defendants incorporate by reference their answers to paragraphs 1 through 316 as if fully set forth herein.

318. Denied.

319. Denied.

320. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 320.

321. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 321.

322. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 322.

323. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 323.

324. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 324.

325. Denied.

326. Denied.

327. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products

constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 327.

328. Denied.

329. Defendants admit they are not expressly licensed under the ’024 patent, but deny that Defendants need a license to that patent.

330. Denied.

331. Denied.

332. Denied.

COUNT XII

Infringement of the ’648 Patent

333. Defendants incorporate by reference their answers to paragraphs 1 through 332 as if fully set forth herein.

334. Denied.

335. Denied.

336. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut

tissue with micron-scale precision.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 336.

337. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 337.

338. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 338.

339. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants deny the remaining allegations of paragraph 339.

340. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit that certain LenSx® marketing materials have illustrated a circle scan as in the first cited image. Defendants deny the remaining allegations of paragraph 340.

341. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 341.

342. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 342.

343. Denied.

344. Denied.

345. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products

constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 345.

346. Denied.

347. Denied.

348. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 348.

349. Denied.

350. Defendants admit they are not expressly licensed under the ’684 patent, but deny that Defendants need a license to that patent.

351. Denied.

352. Denied.

353. Denied.

354. Denied.

COUNT XIII

Infringement of the '903 Patent

355. Defendants incorporate by reference their answers to paragraphs 1 through 354 as if fully set forth herein.

356. Denied.

357. Denied.

358. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 358.

359. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a

sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 359.

360. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 360.

361. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 361.

362. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 362.

363. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit the cited image appears to

be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 363.

364. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "[t]he Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or Frag. Chop and Cylinder patterns may be combined;" "[l]ens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule;" "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete;" "followed by successive x-shaped scans created a few microns apart;" "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule." Defendants deny the remaining allegations of paragraph 364.

365. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 365.

366. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 366.

367. Denied.

368. Denied.

369. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 369.

370. Denied.

371. Denied.

372. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 372.

373. Denied.

374. Defendants admit they are not expressly licensed under the ’903 patent, but deny that Defendants need a license to that patent.

375. Denied.

376. Denied.

377. Denied.

378. Denied.

COUNT XIV

Infringement of the '904 Patent

379. Defendants incorporate by reference their answers to paragraphs 1 through 378 as if fully set forth herein.

380. Denied.

381. Denied.

382. Defendants admit that certain LenSx® marketing materials state that LenSx® is “indicated for use in patients undergoing cataract surgery.... The LenSx® Laser creates incisions through tightly focused femtosecond laser pulses that cut tissue with micron-scale precision.” Defendants admit that LenSx® is indicated for use in anterior capsulotomy and laser phacofragmentation during cataract surgery, as well as in the creation of corneal cuts/incisions during cataract surgery, the creation of a lamellar cut/resection for lamellar keratoplasty, the creation of a penetrating cut/incision for penetrating keratoplasty, and the creation of a corneal flap in patients undergoing LASIK surgery. Defendants deny the remaining allegations of paragraph 382.

383. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the following quoted language: “The LenSx® Laser System uses

focused femtosecond laser pulses to create incisions and to separate tissue within the lens capsule, crystalline lens, and the cornea;” “[t]he light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is photodisrupted at the laser focus;” and a “computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision.” Defendants deny the remaining allegations of paragraph 383.

384. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants admit LenSx® includes an OCT device to image certain structures of the eye, and that it performs a 2D, not a 3D, circle and line scan. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 384.

385. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 385.

386. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 386.

387. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "[t]he Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or Frag. Chop and Cylinder patterns may be combined;" "Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule;" "treatment pattern begins at the programmed posterior depth as an initial x-shaped scan is complete;" "followed by successive x-shaped scans created a few microns apart;" "cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule." Defendants deny the remaining allegations of paragraph 387.

388. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 388.

389. Defendants admit that at least one version of the LenSx® Operator's Manual includes the following quoted language: "[t]he Lens Pattern is used to perform phacofragmentation of the crystalline lens. Lens Patterns may be specified as Chop, Cylinder or Frag. Chop and Cylinder patterns may be combined;" "Lens phacofragmentation patterns are programmed to cut from at least 500 microns above the posterior capsule to at least 500 microns below the anterior capsule;" "treatment

pattern begins at the programmed posterior depth as an initial x-shaped scan is complete;” “followed by successive x-shaped scans created a few microns apart;” “cuts proceed from the deepest point and move anteriorly, ending below the anterior capsule.” Defendants deny the remaining allegations of paragraph 389.

390. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 390.

391. Denied.

392. Denied.

393. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 393.

394. Denied.

395. Denied.

396. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products

constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 396.

397. Denied.

398. Defendants admit they are not expressly licensed under the ’904 patent, but deny that Defendants need a license to that patent.

399. Denied.

400. Denied.

401. Denied.

402. Denied.

COUNT XV
Infringement of the ’356 Patent

403. Defendants incorporate by reference their answers to paragraphs 1 through 402 as if fully set forth herein.

404. Denied.

405. Denied.

406. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 406.

407. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit that photodisruption produces optical breakdown and initiates a plasma-mediated process within the target tissue. Defendants deny the remaining allegations of paragraph 407.

408. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 408.

409. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 409.

410. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 410.

411. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 411.

412. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to

be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 412.

413. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 413.

414. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 414.

415. Denied.

416. Denied.

417. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual includes the following quoted language: “The LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces” and “instructions must be observed,” but deny that the quotations are evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 417.

418. Denied.

419. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator’s Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 419.

420. Defendants admit they are not expressly licensed under the ’356 patent, but deny that Defendants need a license to that patent.

421. Denied.

422. Denied.

423. Denied.

424. Denied.

COUNT XVI
Infringement of the ’548 Patent

425. Defendants incorporate by reference their answers to paragraphs 1 through 424 as if fully set forth herein.

426. Denied.

427. Denied.

428. Defendants admit that at least one version of the LenSx® Operator’s Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 428.

429. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 429.

430. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 430.

431. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 431.

432. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants deny the remaining allegations of paragraph 432.

433. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 433.

434. Defendants admit that at least one version of the LenSx® Operator's Manual includes the quoted language. Defendants admit the cited image appears to

be an image of the LenSx® user interface. Defendants deny the remaining allegations of paragraph 434.

435. Denied.

436. Denied.

437. Defendants admit that at least one version of the Operator's Manual includes the quoted language, but deny that the quotation is evidence of inducing infringement. Defendants deny the remaining allegations of paragraph 437.

438. Denied.

439. Defendants admit that certain Alcon marketing materials state that “[t]he consumables used in conjunction with ALCON® instrument products constitute a complete surgical system,” and that at least one version of the Operator's Manual states that “[t]he LenSx® Laser requires the use of proprietary sterile disposable Patient Interfaces,” but deny that the quotations are evidence of infringement. Defendants deny the remaining allegations of paragraph 439.

440. Defendants admit they are not expressly licensed under the '548 patent, but deny that Defendants need a license to that patent.

441. Denied.

442. Denied.

443. Denied.

444. Denied.

COUNT XVII

Direct Infringement of the Copyrighted Computer Programs

445. Defendants incorporate by reference their answers to paragraphs 1 through 444 as if fully set forth herein.

446. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 446 and therefore deny them.

447. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 447 and therefore deny them.

448. Denied.

449. Defendants admit that Plaintiffs identified certain alleged similarities between the iFS® Laser and the LenSx® software on July 14, 2020 and threatened a suit for copyright infringement. Defendants deny that the July 14, 2020 letter from Plaintiffs provided evidence of copying. Defendants deny the remaining allegations in paragraph 449.

COUNT XVIII

Secondary Liability for Infringement of the Copyrighted Computer Programs

450. Defendants incorporate by reference their answers to paragraphs 1 through 449 as if fully set forth herein.

451. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 451 and therefore deny them.

452. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 452 and therefore deny them.

453. Denied.

454. Denied.

455. Denied.

COUNT XIX

Infringement of the Confidential FDA Submissions and Internal Technical Documentation

456. Defendants incorporate by reference their answers to paragraphs 1 through 455 as if fully set forth herein.

457. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 457 and therefore deny them.

458. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 458 and therefore deny them.

459. Denied.

460. Denied.

COUNT XX

Infringement of the IntraLase Operator's Manual

461. Defendants incorporate by reference their answers to paragraphs 1 through 460 as if fully set forth herein.

462. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 462 and therefore deny them.

463. Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of paragraph 463 and therefore deny them.

464. Denied.

PRAAYER FOR RELIEF

The Second Amended Complaint recites a prayer for relief for which no response is required. To the extent an answer is required, Defendants deny that Plaintiffs are entitled to any remedy or relief.

JURY DEMAND

Defendants join Plaintiffs' request for a jury trial on all issues triable by jury.

GENERAL DENIAL

Defendants deny all allegations in Plaintiffs' Second Amended Complaint not expressly admitted.

DEFENSES

465. Defendants incorporate by reference their answers to paragraphs 1 through 464 as if fully set forth herein.

466. Alcon and AMO, and/or their respective subsidiaries and/or predecessors-in-interest, have competed in the marketplace for laser-ophthalmic-surgery systems for over a decade.

467. Between 2003 and 2006, AMO and Alcon were engaged in several patent-infringement lawsuits related to phacoemulsification systems used during cataract surgery.

468. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

469. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

470. Later in 2010, Alcon acquired LenSx Lasers, Inc., which had developed an image-guided, femtosecond-laser system for cataract surgery called the “LenSx Laser” system.

471. After Alcon acquired LenSx Lasers, Inc., between October 2010 and March 2011, AMO and Alcon exchanged a series of letters in which AMO raised perceived concerns over breaches of confidentiality by ex-AMO employees that had since been hired by Alcon. For instance, in one letter sent from AMO to Alcon on March 11, 2011, AMO claimed that it was “aware of material similarities between our two competing systems.” Upon information and belief, the March 11, 2011 letter was the last such letter AMO sent to Alcon concerning alleged “material similarities” between the parties’ systems until July 2020.

472. In 2014, AMO was presented with an opportunity to acquire a used LenSx Laser system from a customer—Island Eye Surgicenter, LLC—as part of a trade-in for an AMO-developed laser-surgery system. AMO purchased the LenSx Laser system from Island Eye Surgicenter, LLC.

473. [REDACTED] purportedly at the direction of counsel, at least AMO employees Brent Schellhase and Matthew Kraai conducted an investigation of the LenSx Laser system hardware and software.

474. [REDACTED]

[REDACTED]

[REDACTED]

475. Upon information and belief, the investigation was conducted, in part, to obtain additional information about the functionality of the LenSx Laser system as part of a competitive assessment.

476. Upon information and belief, the investigation was conducted, in part, to determine whether [REDACTED]
[REDACTED].

477. Upon information and belief, [REDACTED], individuals acting on AMO's behalf investigated the LenSx Laser system's computer program, including, without limitation, its object code.

478. Upon information and belief, based on that investigation, AMO concluded that: (1) LenSx executable binary files included hundreds of references to file, function, and object names and other text that were identical to those found in AMO's iFS software; (2) the LenSx file system had similar or identical structure to the iFS file system, with some file folders having identical names; and (3) the LenSx system included on-screen instructions identical to those on the iFS system.

479. Upon information and belief, [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

480. Upon information and belief, [REDACTED] AMO and/or outside counsel Perkins Coie determined that there was a likelihood that the LenSx Laser system infringed copyrights owned by AMO sufficient to bring a claim of copyright infringement.

481. AMO, however, did not sue Alcon at that time. Upon information and belief, AMO did not do so, in part, because the allegedly copied code did not have significant value to AMO.

482. Upon information and belief, AMO determined that the allegedly copied code did not have significant value at least in part because the code was not

critical to the functionality specific to femtosecond-laser-assisted cataract surgery (“FLACS”) machines, and could be re-coded with limited effort.

483. Upon information and belief, AMO determined that the allegedly copied code did not have significant value at least in part because it had recently acquired a company—Optimedica Corp.—and had decided to use Optimedica’s system and software code (and not the software code that AMO believed had been copied) to develop a rival system to the LenSx Laser system.

484. AMO (and subsequently J&J) did not take any steps to provide Alcon notice that the LenSx Laser system allegedly contained AMO’s purportedly copyrighted code, or [REDACTED]
[REDACTED], prior to July 2020.

485. After AMO had conducted the investigation in or around 2014 and/or 2015, AMO (and subsequently J&J) and Alcon [REDACTED]
[REDACTED]
[REDACTED].

486. Upon information and belief, AMO knowingly allowed Alcon to continue using the allegedly infringing code, and consented explicitly or implicitly to Alcon’s alleged continued infringement of AMO’s purportedly copyrighted code from 2014 until 2020.

487. AMO asserted claims of copyright infringement in 2020 based on the 2014 investigation of the LenSx Laser system and software.

488. AMO reasonably should have provided Alcon notice [REDACTED]

[REDACTED] as a result of its 2014 investigation of the LenSx Laser system, so that Alcon would have had the opportunity to investigate and timely address AMO's concerns.

489. AMO waited for nearly six years, while sales of the LenSx Laser system grew substantially, before informing Alcon of its potential copyright infringement claim in 2020.

490. AMO seeks actual damages for Alcon sales that could have been rendered non-infringing had AMO provided Alcon notice of [REDACTED]
[REDACTED]. Had AMO notified Alcon [REDACTED] in an attempt to mitigate its damages, Alcon could have developed new software, mitigating the flow of damages. AMO claims that with each placement of a LenSx, damages from allegedly lost sales of patient interfaces continue for at least ten years into the future beyond the initial placement of the LenSx.

491. Plaintiffs seek equitable remedies, including injunctive relief and disgorgement of Defendants' profits. AMO, however, was on notice [REDACTED]

█████ of the same facts upon which it based its Amended Complaint in this case.

Alcon reasonably relied on AMO's six years of inaction.

492. AMO's lack of diligence has caused prejudice to Alcon, at least by unreasonably inflating the potential equitable award, including, without limitation, disgorgement of Alcon's profits, especially when Alcon could have remediated the alleged infringement years prior to the filing of Plaintiffs' copyright claim.

493. Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in the Second Amended Complaint, Defendants rely upon the following defenses, whether pled as an affirmative defense or otherwise:

First Defense (Non-Infringement)

494. Defendants do not infringe (literally or under the doctrine of equivalents), and at all relevant times to this action have not infringed, any valid and enforceable claim of the Asserted Patents.

Second Defense (Invalidity)

495. The Asserted Patents are invalid for failure to satisfy one or more of the conditions and requirements of patentability set forth in 35 U.S.C. §§ 101 et seq., including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, or under any of the judicially created doctrines of invalidity.

Third Defense (Failure to State a Claim)

496. The amended complaint fails to state a claim upon which relief can be granted.

Fourth Defense (No Willful Infringement)

497. Defendants have not willfully infringed, and do not willfully infringe, any valid and enforceable claim of any of the Asserted Patents.

Fifth Defense (No Exceptional Case)

498. Defendants' actions in defending this case do not give rise to an exceptional case in Plaintiffs' favor under 35 U.S.C. § 285.

Sixth Defense (Prosecution History Estoppel)

499. Plaintiffs are barred under the doctrine of prosecution history estoppel from asserting any scope of the Asserted Patents that would cover the accused products because of statements and amendments made during prosecution of the applications that led to the Asserted Patents.

Seventh Defense (No Injunctive Relief)

500. Plaintiffs are not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction because they cannot meet any of the multi-factor tests required for demonstrating a

right to such injunctive relief and because of Plaintiffs' delay in seeking to enforce the Asserted Patents and the Asserted Copyrights.

Eighth Defense (*De Minimis* Use)

501. Plaintiffs' claims based on the Asserted Copyrights are barred, in whole or in part, by the doctrine of *de minimis* use.

Ninth Defense (Non-Infringement of Copyright)

502. Plaintiffs' claims are barred, in whole or in part, because Defendants do not infringe and have not infringed the copyrights at issue, including without limitation pursuant to the doctrines of scènes à faire, merger, and/or other limits on the scope of copyright protection.

Tenth Defense (Statute of Limitations)

503. Plaintiffs' claims based on the Asserted Copyrights are barred, in whole or in part, by the statute of limitations. 17 U.S.C. § 507(b).

Eleventh Defense (Laches/Delay)

504. Defendants repeat and re-allege paragraphs 465 through 493 as if fully set forth herein.

505. The equitable relief sought by Plaintiffs based on the Asserted Copyrights is barred, in part, by laches and Plaintiffs' delay.

506. Plaintiffs are not entitled to injunctive relief or disgorgement of Defendants' profits after AMO became aware of its potential claim and elected not to bring suit or otherwise notify Alcon.

Twelfth Defense (Failure to Mitigate Damages)

507. Defendants repeat and re-allege paragraphs 465 thorough 493 as if fully set forth herein.

508. Plaintiffs' damages based on the Asserted Copyrights are barred, in whole or in part, because Plaintiffs failed to mitigate their damages.

509. As a result of their failure to mitigate damages, Plaintiffs are not entitled to any actual damages that accrued after the date on which, had they informed Defendants of the alleged infringement, their damages could have been mitigated.

Thirteenth Defense (Acquiescence)

510. Defendants repeat and re-allege paragraphs 465 thorough 493 as if fully set forth herein.

511. Plaintiffs' claims based on the Asserted Copyrights are barred, in whole or in part, under the doctrine of estoppel by acquiescence.

512. As a result of their acquiescence, Plaintiffs are not entitled to injunctive relief or disgorgement of Defendants' profits after AMO became aware of its potential claim and acquiesced to Alcon's alleged use of Plaintiffs' copyrights.

ADDITIONAL DEFENSES

513. Defendants reserve the right to assert any additional defenses or counterclaims that discovery may reveal.

ALCON'S DECLARATORY JUDGMENT COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Alcon Vision LLC, Alcon Vision, LLC, Alcon Laboratories, Inc. and Alcon Research, LLC (collectively, "Alcon" or "Defendants") demand a trial by jury on all issues so triable and assert the following counterclaims against Plaintiffs/Counterclaim-Defendants AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc. (collectively, "AMO"):

PARTIES

1. Alcon Vision LLC ("Alcon Vision") is a Delaware corporation with a principal place of business at 6201 South Freeway, Fort Worth, Texas.
2. Alcon Laboratories, Inc. ("Alcon Laboratories") is a Delaware corporation with a principal place of business at 6201 South Freeway, Fort Worth, Texas.
3. Alcon Research, LLC ("Alcon Research") is a Delaware company with a principal place of business at 6201 South Freeway, Fort Worth, Texas.
4. Upon information and belief, AMO Development, LLC ("AMO Development") is a Delaware company with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. Upon information and belief, AMO Development is an indirect subsidiary of Johnson & Johnson Surgical Vision, Inc. ("JJSV").

5. Upon information and belief, AMO Manufacturing USA, LLC (“AMO Manufacturing”) is a Delaware company with a principal place of business at 510 Cottonwood Drive, Milpitas, California. Upon information and belief, AMO Manufacturing is an indirect subsidiary of JJSV.

6. Upon information and belief, AMO Sales and Service, Inc. (“AMO Sales and Service”) is a Delaware corporation with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. Upon information and belief, AMO Sales and Service is an indirect subsidiary of JJSV.

7. Upon information and belief, JJSV” is a Delaware corporation with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. According to the FDA’s website, JJSV is the owner/operator of AMO Manufacturing, manufacturer of CATALYS®.

NATURE OF THE ACTION

8. Defendants seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent No. 8,394,084 (“the ’084 patent”), U.S. Patent No. 8,403,921 (“the ’921 patent”), U.S. Patent No. 8,425,497 (“the ’497 patent”), U.S. Patent No. 8,500,724 (“the ’724 patent”), U.S. Patent No. 8,709,001 (“the ’001 patent”), U.S. Patent No. 9,095,415 (“the ’415 patent”), U.S. Patent No. 9,101,448 (“the ’448 patent”), U.S. Patent No. 9,107,732 (“the ’732 patent”), U.S. Patent No.

9,125,725 (“the ’725 patent”), U.S. Patent No. 9,233,023 (“the ’023 patent”), U.S. Patent No. 9,233,024 (“the ’024 patent”), U.S. Patent No. 9,474,648 (“the ’648 patent”), U.S. Patent No. 9,693,903 (“the ’903 patent”), U.S. Patent No. 9,693,904 (“the ’904 patent”), U.S. Patent No. 10,376,356 (“the ’356 patent”), and U.S. Patent No. 10,709,548 (“the ’548 patent”), (collectively, the “AMO Asserted Patents”) are invalid and/or not infringed. The ’084 patent, ’921 patent, ’497 patent, ’724 patent, ’001 patent, ’415 patent, ’448 patent, ’732 patent, ’725 patent, ’648 patent, ’903 patent, and ’904 patent are referred to collectively herein as the “Palanker Patents.” The ’023 patent, ’024 patent, ’356 patent, and ’548 patent are referred to collectively herein as the “Culbertson Patents.”

JURISDICTION AND VENUE

9. This Court has exclusive subject matter jurisdiction over Alcon’s patent infringement claims pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338; and the patent laws of the United States, 35 U.S.C. § 1 et seq.

10. This Court has personal jurisdiction over each of AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc. because each has subjected itself to the jurisdiction of this Court by filing their Complaint. Furthermore, AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc., are organized and existing under the laws of the State of Delaware.

11. AMO Development, LLC purports to be the owner by assignment of each of the AMO Asserted Patents. AMO Development, LLC, AMO Manufacturing USA, LLC, and AMO Sales and Service, Inc. purport to be the owners of the entire right, title, and interest in and to the AMO Asserted Patents.

12. Venue in this Court is proper based on the choice of forum by Plaintiffs and pursuant to 28 U.S.C. §§ 1391(b)-(c), and 1400(b).

AMO'S CLAIMS AGAINST ALCON

AMO's Asserted Patents Are Invalid

13. AMO filed a lawsuit against Alcon LenSx, Inc., Alcon Vision, LLC, Alcon Laboratories, Inc., and Alcon Research, LLC on June 23, 2020 asserting that the LenSx® Laser infringes the Palanker patents. On September 28, 2020, AMO amended their complaint, asserting that the LenSx® Laser also infringes the Culbertson Patents. On June 17, 2021, AMO again amended their complaint.

14. The independent claims of the Palanker Patents all overlap in scope, and include the same basic system or method of performing an anterior capsulotomy or lens fragmentation via the use of a) a pulsed laser, b) an OCT or other imaging system, c) an optical scanning system, and d) a controller coupled to all three. This combination is not a patentable invention but an obvious and non-novel combination of the prior art.

15. The Palanker Patents seek to claim well-known, established systems and methods of performing FLACS procedures by combining known uses of femtosecond lasers with an established OCT imaging system and scanning system.

16. The independent claims of the Culbertson Patents all overlap in scope, and include the same basic system or method of performing a cataract incision and relaxation incision during a FLACS procedure. This combination is not a patentable invention but an obvious and non-novel combination of the prior art.

17. The Culbertson Patents seek to claim well-known, established systems and methods of performing FLACS procedures by combining the known use of FLACS systems to perform a cataract incision with established methods of performing relaxation incisions during cataract surgery.

18. Based on the foregoing, it is clear that the AMO Asserted Patents are invalid and Defendants are entitled to a declaratory judgment so stating.

Femtosecond Lasers Were Standard in Ophthalmological Surgery by the 2000s

19. The use of lasers with “ultrashort” pulses of light to cut tissue dates back several decades. By the late 1980s, ultrashort pulsed lasers established themselves as the modality of choice for many surgical procedures where propagating thermal effects are to be suppressed, including for cataract surgery. U.S. U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; among other sources, describes the development of ultrashort pulsed lasers.

20. Such “ultrashort pulsed lasers” emit pulses of light that are on the order of picoseconds (10^{-12} s) or shorter in length, and include “femtosecond lasers,” which emit pulses of light that are on the order of a few to several hundred femtoseconds (10^{-15} s) in length.

21. The first studies exploring the laser-tissue interaction of femtosecond lasers and the resulting retinal damage date back to the late 1980s, including, but not limited to Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987).

22. As scientists developed lasers with shorter and shorter pulses, the applications for such lasers naturally grew. In general, femtosecond lasers exhibited improved outcomes over lasers with longer pulse lengths. In particular, cuts in optical tissue created with a femtosecond laser were more precise, more efficient and caused less damage.

23. Numerous publications from the late 1980s and 1990s describe these developments, including David Stern, *Corneal Ablation by Nanosecond, Picosecond, and Femtosecond Lasers at 532 and 625 nm*, Arch. Ophthalmol. (1989) (“Excisions made with picosecond and femtosecond lasers were ultrastructurally superior to those made with nanosecond lasers.”); F.H. Loesel, *Non-thermal ablation of neural tissue with femtosecond laser pulses*, 66 Appl. Phys. B. 121, 125 (1998) (“the shorter femtosecond pulses still ablate a higher amount of neural tissue than

the picosecond Nd:YLF laser pulses...” and “with the Nd:YAG or CO₂ laser, the observed collateral damage is about two orders of magnitude larger than with the femtosecond laser system.”).

24. Because of these advantages, lasers were already being used in the 1980s to perform the specific anterior capsulotomy procedure that is part of modern cataract surgery. Paul M. Woodward et al., *Anterior Capsulotomy Using A Neodymium YAG Laser*, 16 Annals of Ophthalmology 6, 534, 538-39 (study performing 42 anterior capsulotomies prior to cataract surgery concludes that performing the procedure with an a laser “has immediate appeal” because “[t]he opening in the capsule can be precisely made without entering the eye with an instrument,” “[t]here is no stress placed on the zonules, no capsular tags, no extensions of the capsulotomy into the posterior capsule,” and “opening the capsule prior to cataract surgery leads to hydration of the cortex”).

25. In a variety of publications, ophthalmologists had noted during this time that femtosecond lasers were well known for better outcomes than lasers with longer pulses. These publications included Carmen A. Puliafito et al., *Laser Surgery of the Lens: Experimental Studies*, 90 American Academy of Ophthalmology 8, 1007, 1011 (1983) (noting that lower pulse energy is preferred as “Pulse energy and the cone angle of the laser radiation are the two variables that must be optimized to avoid retinal injury during laser surgery in the anterior segment of the eye.”); U.S.

Patent No. 6,325,792 to Swinger et al., published December 4, 2001 (“the present invention uses short duration laser pulses from about 10 femtoseconds to 2 picoseconds to reduce inflicted damage to target tissues ” and noting using a femtosecond laser to perform anterior capsulotomies was preferred as “[t]he gentle femtosecond pulse width laser reduces acoustic shock and allows the surgeon to operate closer to the retina....”).

26. Indeed, the use of lasers in anterior capsulotomies was accepted by the early-1980s as demonstrated by an *in vivo* study conducted between 1978 and 1982 in which an anterior capsulotomy was performed on 2,174 participants using an ultra-short pulsed laser. *See* Daniele Aron-Rosa et al., *Use of pulsed ps NdYag laser in 6664 cases*, Am. Intra-Ocular Implant Soc. J., Vol. 10 (1984).

27. The founders of Defendant Alcon Lensx, Inc.’s predecessor, Tibor Juhasz and Ronald M. Kurtz, foresaw the application of femtosecond lasers to corneal surgery in the late 1990s and early 2000s. They published this insight in leading ophthalmology publications for these insights, including Tibor Juhasz et al., *Corneal Refractive Surgery with Femtosecond Lasers*, IEEE Journal of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999) (“[b]y improving existing procedures and enabling entirely new ones, femtosecond laser technology has the potential to become the preferred corneal laser scalpel in the 21st Century”); Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology

and Applications, 745, 746 (2003) (femtosecond lasers “offer[] the potential for an ideal surgical scalpel”).

28. By the early 2000s, clinical trials took off using femtosecond lasers in eye surgery. The first clinical results were published in 2003 in the Journal of Refractive Surgery. *See Ratkay-Traub, First Clinical Results With the Femtosecond Neodymium-Glass Laser in Refractive Surgery*, J. Refract Surg. (2003).

Optical Coherence Tomography Guided Optical Surgery Was Developed in the 1990s

29. The above advances in tissue cutting techniques with the advent of femtosecond lasers naturally led to a need for more precise tools for guiding the laser cuts. In the late 1980s and early 1990s, computerized image-guided laser control systems allowed the cutting process to run automatically, minimizing operator oversight and error, with feedback based on the actual imaged eye structures. *See International Publication No. WO 1994/009849 to Swinger et al.*, published May 11, 1994 (when performing an anterior capsulotomy with a femtosecond laser, the “cutting process can be totally computerized once the reference point on the capsule has been fixed.”); U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992 (Eye surgeons “well appreciated that the limitations on the achievable accuracy and control of laser surgical instruments today is no longer paced by the development of laser technology, but by the imaging and tracking technologies needed to effectively use the laser.”).

30. For example, in the late 1980s, ophthalmologic surgeons were already using confocal microscopy to guide automated laser surgical cuts. U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992. Computer-controlled image-guided laser systems became commonplace in the 1990s for eye surgery. *See, e.g.*, Thomas Hoppeler et al., *Preliminary clinical results with the ISL laser*, SPIE VOL. 1644 Ophthalmic Technologies II, 96, 96 (1992) (“Different 3-dimensional patterns for the laser beam can be defined on the built-in computer system. These patterns are then delivered to the tissue precisely, controlled through the built-in motion control unit of the slitlamp.”); U.S. Patent No. 5,520,679 to Lin, published May 28, 1996 (“In the present invention, a computer-controlled scanning device is able to perform the laser thermokeratoplasty procedure”).

31. These early computer controlled devices disclosed how laser operation could be done automatically, as “by laying the template in effect on the computer-generated image of the region, he can then execute a pre-stored program to automatically execute the surgery in a precisely controlled preselected manner.” U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992. One invention in the late 1980s disclosed a “unique integration of several such diverse aspects (including mapping, imaging, tracking, precision laser cutting and user interface), precisely yet inexpensively, into a fully automated workstation.” U.S. Patent 6,099,522 to Knopp et al., published August 8, 2000.

32. As optical imaging techniques advanced, such techniques were naturally incorporated into these image guided systems. For example, Optical Coherence Tomography (OCT) was the next evolution of imaging technology being investigated for use in ophthalmology. The first use of OCT to create a “high resolution cross-sectional image of structure in the anterior segment of the human eye *in vivo*,” including to image cataracts to their full thickness, was in 1994. Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994). As described by Dr. Izatt, OCT was a “high-quality tomographic imaging for the measurement of anterior eye structures and anterior chamber depth, corneal thickness, curvature, the anterior angle and anterior angle region morphologic characteristics, iris structure and cataract progression in the crystalline lens” and therefore had “potential... as a diagnostic procedure for ophthalmologic examination of the anterior eye.” *Id.* at 1589.

33. By the late 1990s, OCT was a well-known method of imaging the human eye with more precision and depth than ever before. Laser systems and an OCT “were coupled together using an adjustable beam-splitter enabling OCT-imaging before and immediately after the laser exposure.” Reginald Birngruber et al., *In vivo imaging of the development of linear and nonlinear retinal laser effects using optical coherence tomography in correlation with histopathological findings*,

SPIE Vol. 2391, 21, 22 (1995). OCT provided a mechanism for realistic imaging for various applications - “We have demonstrated the use of high-speed, real time OCT imaging for guiding the placement and monitoring the dynamic changes of surgical laser ablation in a variety of tissues.” Stephen A. Boppart et al., *High-Resolution Optical Coherence Tomography-Guided Laser Ablation of Surgical Tissue*, 82 J. of Surgical Research, 275, 281 (1998). Unsurprisingly, by 2005, there were numerous publications disclosing combinations of an OCT with a laser, including for use in cataract surgery. EP1231496A2 to Hellmuth et al., published August 14, 2002 (disclosing the use of OCT for cataract surgery); U.S. Pat. Pub. No. 2005/0203422 to Wei, filed February 10, 2005 (same).

34. As a result, OCT guided laser cutting systems were described, and used in optical surgery decades ago. See U.S. Patent No. 6,482,199 to Neev, published November 19, 2002 (Disclosing a laser system which acted with a feedback means created by OCT, wherein “[t]he feedback means is operatively coupled to the laser.”); U.S. Patent No. 6,787,733 Lubatschowski et al., published September 7, 2004 (“Linking the OCT technique with imaging methods for visualisation of the material area to be machined or already machined and [] use of the OCT results for controlling material machining is particularly preferred.”). By leveraging OCT technology, optical surgeons could look further and more clearly into the eye,

opening up the field to surgical procedures requiring deep and more precise cutting tools, such as cataract surgery.

Relaxing Incisions Were Known to Be Performed During Cataract Surgery

35. Relaxing incisions are partial depth incisions in the cornea, limbus, or sclera which have long been used to correct astigmatism. As early as 1998, it was recognized that “[a]n important goal in cataract surgery is to control and, in some patients, to reduce corneal astigmatism,” and “[t]he treatment goal is choosing a surgical strategy that permits correction of the patient’s total refractive error in one operation,” via the use of limbal relaxing incisions during cataract surgery. K. Budak et al., *Limbal relaxing incisions with cataract surgery*, J. Cataract Refract. Surg. 1998; 24:503-508. Numerous other references describe the combination of cataract surgery with relaxing incisions. See, e.g., H. Bayramlar et al., “Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery,” J. Cataract Refract. Surg., 2003, 29:723-728 (“In conclusion, LRIs are a simple, safe, and effective method of correcting primary or surgically induced mixed astigmatism as well as astigmatism during cataract surgery.”); L. Wang et al., *Peripheral corneal relaxing incisions combined with cataract surgery*, J. Cataract Refract. Surg., 2003; 29:712-722 (In conclusion, PCRIs are a practical, simple, effective method to reduce preexisting astigmatism during cataract surgery.”); Louis D. Nichamin, *Treating astigmatism at the time of cataract surgery*, Curr. Opin.

Ophthalmol. 2003, 14:35-38. By 2005, relaxation incisions were “often performed at the end of cataract surgery, for example, to eliminate an astigmatism that was induced by the main cataract incision, or that had previously existed.” U.S. Pat. Pub. No. 2005/0241653 to Van Heugten et al., published November 3, 2005.

36. Unsurprisingly, it had also long been recognized that relaxing incisions could be performed with a laser. For instance, U.S. Patent No. 5,549,632 to Shui Lai, published August 27, 1996, teaches using a laser to make “excisions in the cornea... for performing radial keratotomies or making T-cuts, to correct myopia, hyperopia, or astigmatism.” Lai also teaches using the same laser to create holes in the anterior capsule of the eye, i.e., anterior capsulotomy. Similarly, U.S. Patent No. 6,325,792 to Swinger et al., published December 4, 2001, teaches using a laser to create relaxation incisions in addition to anterior capsulotomy.

37. As a result, it was clear that femtosecond lasers could be used to perform relaxing incisions during cataract surgery. Moreover, by the time of the Culbertson patents, femtosecond lasers combined with an OCT were known in the art. For instance, the ’084 patent first published on August 31, 2006, and is therefore prior art to the Culbertson patents under 35 U.S.C. § 102(a) and (e). It was thus not inventive to use a femtosecond laser with an OCT to make a relaxing incision during cataract surgery.

COUNT I

**DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '084
PATENT**

38. Defendants repeat and re-allege paragraphs 1-37 as if fully set forth herein.

39. Plaintiffs have brought claims against Defendants alleging infringement of at least claim 1 of the '084 patent.

40. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '084 patent.

41. LenSx® does not meet each and every limitation of claim 1 of the '084 patent, which recites:

A system for cataract surgery on an eye, comprising:

a pulsed laser configured to produce a treatment beam which creates dielectric breakdown in a focal zone of the treatment beam within one or more tissue structures of a cataractous crystalline lens;

a three-dimensional, optical coherence tomography imaging assembly capable of creating a continuous depth profile of the anterior portion of the cataractous crystalline lens, the profile comprising information regarding the location of a capsule of the cataractous crystalline lens and structures within the crystalline lens, by detecting remitted illumination light from locations distributed throughout a volume of the cataractous crystalline lens, and generating signals based upon the remitted light;

an optical scanning system configured to position a focal zone of the treatment beam to a targeted location in three dimensions in the crystalline lens; and

one or more controllers operatively coupled to the laser, optical system, and imaging assembly, and programmed to automatically:

scan tissues of the patient's eye with the imaging assembly so as to generate image data signals to create a continuous depth profile of at least the anterior portion of the lens;

identify one or more boundaries of the one or more tissue structures of the cataractous crystalline lens based at least in part on the image data;

identify one or more treatment regions based upon the boundaries; and

operate the optical scanning system with the pulsed laser to produce a treatment beam directed in a pattern based on the one or more treatment regions so as to create a capsulotomy in the anterior portion of the lens, the treatment beam having a pulse repetition rate between about 1 kHz and about 1,000 kHz, and a pulse energy between about 1 microjoule and about 30 microjoules.

42. LenSx® does not have a "three-dimensional, optical coherence tomography imaging assembly" capable of creating a "continuous depth profile" by detecting light from "locations distributed throughout a volume" of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

43. Further, the system of claim 1 must "automatically" (1) "scan tissues" (2) "identify one or more boundaries" (3) "identify one or more treatment regions" and (4) "operate ... the pulsed laser to produce a treatment beam." LenSx® does not operate "automatically," as it requires surgeon input.

44. In addition, the “optical scanning system” of claim 1 must be “configured to” position the treatment beam and must be limited to the disclosed embodiments in the specification. The ’084 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

45. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’084 patent for the reasons stated in paragraphs 42-44 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’084 patent because Defendants do not specifically intend for another party to infringe the ’084 patent and do not know that the other party’s acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the ’084 patent. Defendants also have no knowledge of any direct infringement of the ’084 patent by any third party.

46. Moreover, as explained in paragraphs 42-45, Defendants do not contribute to infringement of the '084 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '084 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '084 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

47. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components

are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

48. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '084 patent, either literally or under the doctrine of equivalents.

49. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT II

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '084 PATENT

50. Defendants repeat and re-allege paragraphs 1-49 as if fully set forth herein.

51. Defendants allege that the claims of the '084 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

52. At least claim 1 of the '084 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '084 patent does not contain a written description sufficient to be in possession of separate scanners for the treatment beam and imaging assembly as required by at least claim 1 of the '084 patent. Nor does the specification of the '084 patent contain a written description sufficient to be in possession of a "three-dimensional" OCT imaging assembly.

53. At least claim 1 of the '084 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention.

For instance, the specification of the '084 patent does not contain an enabling description of a “three-dimensional” OCT.

54. At least claim 1 of the '084 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required “controllers” of at least claim 1 are indefinite because the specification of the '084 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

55. At least claim 1 of the '084 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '084 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '084 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

56. At least claim 1 of the '084 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in

claim 1 of the '084 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '084 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

57. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '084 patent.

58. Defendants are entitled to a declaration that one or more claims of the '084 patent are invalid.

59. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT III

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '921 PATENT

60. Defendants repeat and re-allege paragraphs 1-59 as if fully set forth herein.

61. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '921 patent.

62. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '921 patent.

63. LenSx® does not meet each and every limitation of claim 1 of the '921 patent, which recites:

A system for cataract surgery on an eye of a patient, comprising:

a laser assembly for generating a pulsed laser treatment beam that creates dielectric breakdown in a focal zone of

the treatment beam within tissues of the patient's eye so as to effect a cataract surgery procedure;

an optical coherence tomography (OCT) 3-Dimensional imaging system configured for imaging tissue of a cataractous crystalline lens of the patient;

an optical scanning system configured for positioning the focal zone of the treatment beam to targeted locations of the crystalline lens; and

a computer control system operatively coupled to the laser assembly, the imaging system, and the optical scanning system, and programmed to automatically:

acquire image data from locations distributed throughout a volume of the cataractous crystalline lens using the imaging system;

construct one or more images of the patient's eye tissues from the image data, comprising an image of at least a portion of the crystalline lens;

construct an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

operate the optical scanning system and laser assembly to direct a treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

64. LenSx® does not have the capability of “acquir[ing] image data from locations distributed throughout a volume” of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

65. Further, the system of claim 1 must “automatically” (1) “acquire image data” (2) “construct one or more images” (3) “construct an anterior capsulotomy cutting region” and (4) “operate … to direct a treatment beam.” LenSx® does not operate “automatically,” as it requires surgeon input.

66. In addition, the “optical scanning system” of claim 1 must be “configured for” positioning the treatment beam and must be limited to the disclosed embodiments in the specification. The ’921 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

67. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’921 patent for the reasons stated in paragraphs 64-66 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’921 patent because Defendants do not specifically intend for another party to infringe the ’921 patent and do not know that the other party’s acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and

do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '921 patent. Defendants also have no knowledge of direct infringement of the '921 patent by any third party.

68. Moreover, as explained in paragraphs 64-67, Defendants do not contribute to infringement of the '921 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '921 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '921 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

69. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to,

not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

70. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '921 patent, either literally or under the doctrine of equivalents.

71. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT IV

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '921 PATENT

72. Defendants repeat and re-allege paragraphs 1-71 as if fully set forth herein.

73. Defendants allege that the claims of the '921 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

74. At least claim 1 of the '921 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '921 patent does not contain a written description sufficient to be in possession of separate scanners for the treatment beam and imaging assembly as required by at least claim 1 of the '921 patent. Nor does the specification of the '921 patent contain a written description sufficient to be in possession of a “3-Dimensional” OCT imaging system.

75. At least claim 1 of the '921 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention.

For instance, the specification of the '921 patent does not contain an enabling description of a “3-Dimensional” OCT.

76. At least claim 1 of the '921 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required “computer control system” of at least claim 1 is indefinite because the specification of the '921 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

77. At least claim 1 of the '921 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '921 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '921 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

78. At least claim 1 of the '921 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in

claim 1 of the '921 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '921 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

79. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '921 patent.

80. Defendants are entitled to a declaration that one or more claims of the '921 patent are invalid.

81. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT V

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '497 PATENT

82. Defendants repeat and re-allege paragraphs 1-81 as if fully set forth herein.

83. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '497 patent.

84. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '497 patent.

85. LenSx® does not meet each and every limitation of claim 1 of the '497 patent, which recites:

A method of making an incision in eye tissue during a cataract surgical procedure, the method comprising:

operating an imaging system, coupled to an electronics control system comprising a computer, so as to acquire image data from locations distributed throughout a volume

of a crystalline lens of a patient and construct one or more images of the patient's eye tissues from the image data, wherein one or more images include an image of at least a portion of the crystalline lens;

identifying, using the control system, a cutting region based on the image data, the cutting region being at least partially defined by an anterior cutting boundary and a posterior cutting boundary and including a portion of the crystalline lens;

generating a beam of light using a pulsed laser system guided by the control system so as to scan the beam in a pattern within the cutting region and segment the crystalline lens into a plurality of pieces for subsequent removal, the segmentation of the crystalline lens including:

focusing the beam at a first focal point located at a first depth in the eye tissue;

scanning the beam on the eye while focused at the first depth so as to create an incision pattern within the cutting region at the first depth;

focusing the beam at a second focal point located at a second depth in the eye tissue different than the first depth; and

scanning the beam on the eye while focused at the second depth so as to create an incision pattern within the cutting region at the second depth.

86. LenSx® does not have “an imaging system” capable of “acquir[ing] image data from locations distributed throughout a volume” of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

87. Further, Defendants do not infringe the '497 patent because Defendants do not practice the method disclosed. At a minimum, and without limitation,

Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '497 patent for the reasons alleged in paragraph 86 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '497 patent because Defendants do not specifically intend for another party to infringe the '497 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '497 patent. Defendants also have no knowledge of direct infringement of the '497 patent by any third party.

88. Moreover, as explained in paragraphs 86-87, Defendants do not contribute to infringement of the '497 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '497 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '497 patent and that it is not a staple article of commerce that has no substantial

noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

89. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '497 patent, either literally or under the doctrine of equivalents.

90. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VI

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '497 PATENT

91. Defendants repeat and re-allege paragraphs 1-90 as if fully set forth herein.

92. Defendants allege that the claims of the '497 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

93. At least claim 1 of the '497 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the

specification of the '497 patent does not contain a written description sufficient to be in possession of separate scanners for the laser system and imaging system as required by at least claim 1 of the '497 patent. Nor does the specification of the '497 patent contain a written description sufficient to be in possession of an imaging system capable of acquiring "image data from locations distributed throughout a volume."

94. At least claim 1 of the '497 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention. For instance, the specification of the '497 patent does not contain an enabling description of an imaging system capable of acquiring "image data from locations distributed throughout a volume."

95. At least claim 1 of the '497 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '497 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

96. At least claim 1 of the '497 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '497 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a

printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '497 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

97. At least claim 1 of the '497 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '497 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '497 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution*

Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

98. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '497 patent.

99. Defendants are entitled to a declaration that one or more claims of the '497 patent are invalid.

100. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VII

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '724 PATENT

101. Defendants repeat and re-allege paragraphs 1-100 as if fully set forth herein.

102. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '724 patent.

103. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '724 patent.

104. LenSx® does not meet each and every limitation of claim 1 of the '724 patent, which recites:

A method for laser cataract surgery that protects the retina of the eye from laser exposure, comprising:

generating, using a computer, an image of at least a portion of a crystalline lens of the eye based on detecting remitted light from locations distributed throughout a volume of the crystalline lens;

processing data including the image data so as to determine a targeted treatment region in the lens of the eye, wherein the targeted treatment region comprises an axially-elongated cutting zone transecting the anterior capsule and does not transect the posterior capsule of the lens;

directing a laser beam, under computer guided control, in a first pattern to photodisrupt at least a portion of the lens tissue of the eye to create a light scattering region; and

subsequently directing the laser beam, under computer guided control, in a second pattern in lens tissue anterior to the light scattering region so as to photodisrupt at least a portion of the targeted region, thereby effecting patterned laser cutting of lens tissue for subsequent removal of pieces or segments of lens tissue.

105. LenSx® cannot “generat[e], using a computer, an image” “from locations distributed throughout a volume of the crystalline lens.” Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

106. Further, Defendants do not infringe the ’724 patent because Defendants do not practice the method disclosed. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’724 patent for the reasons alleged in paragraph 105 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’724 patent because Defendants do not specifically intend for another party to infringe the ’724 patent and do not know that the other party’s acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the ’724 patent. Defendants also have no knowledge of direct infringement of the ’724 patent by any third party.

107. Moreover, as explained in paragraphs 105-106, Defendants do not contribute to infringement of the ’724 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of

the '724 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '724 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

108. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '724 patent, either literally or under the doctrine of equivalents.

109. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT VIII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '724 PATENT

110. Defendants repeat and re-allege paragraphs 1-109 as if fully set forth herein.

111. Defendants allege that the claims of the '724 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

112. At least claim 1 of the '724 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '724 patent does not contain a written description sufficient to be in possession of separate scanners as required to “generat[e] ... an image” and “direct[] the laser beam” by at least claim 1 of the '724 patent. Nor does the specification of the '724 patent contain a written description sufficient to be in possession of a computer capable of acquiring “an image... from locations distributed throughout a volume.”

113. At least claim 1 of the '724 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention. For instance, the specification of the '724 patent does not contain an enabling description of a computer capable of acquiring “an image... from locations distributed throughout a volume.”

114. At least claim 1 of the '724 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required “computer guided control” of at

least claim 1 is indefinite because the specification of the '724 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

115. At least claim 1 of the '724 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '724 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '724 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

116. At least claim 1 of the '724 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '724 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing

so. For instance, claim 1 of the '724 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art

117. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '724 patent.

118. Defendants are entitled to a declaration that one or more claims of the '724 patent are invalid.

119. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT IX

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '001 PATENT

120. Defendants repeat and re-allege paragraphs 1-119 as if fully set forth herein.

121. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '001 patent.

122. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '001 patent.

123. LenSx® does not meet each and every limitation of claim 1 of the '001 patent, which recites:

A method for cataract surgery on an eye of a patient using a pulsed laser surgical system, comprising:

operating an imaging system so as to acquire image data from locations distributed throughout a volume of a cataractous crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens;

constructing, using a computer system, an anterior capsulotomy cutting region based on the image data, the capsulotomy cutting region comprising an anterior cutting boundary axially spaced from a posterior cutting boundary so as to define an axially-elongated cutting zone transecting the anterior capsule; and

operating the surgical system to direct a pulsed laser treatment beam in a pattern based on the anterior capsulotomy cutting region so as to create an anterior capsulotomy in the crystalline lens.

124. LenSx® does not “acquire image data from locations distributed throughout a volume” of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

125. Further, Defendants do not infringe the '001 patent because Defendants do not practice the method disclosed. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '001 patent for the reasons alleged in paragraph 124 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '001 patent because Defendants do not specifically intend for another party to infringe the '001 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '001 patent. Defendants also have no knowledge of direct infringement of the '001 patent by any third party.

126. Moreover, as explained in paragraphs 124-125, Defendants do not contribute to infringement of the '001 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '001 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '001 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

127. Defendants also do not infringe under 35 U.S.C. § 271(f). For one, § 271(f) does not apply to method claims, and the '001 patent is only directed to method claims. In any case, Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or

from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

128. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '001 patent, either literally or under the doctrine of equivalents.

129. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT X

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '001 PATENT

130. Defendants repeat and re-allege paragraphs 1-129 as if fully set forth herein.

131. Defendants allege that the claims of the '001 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

132. At least claim 1 of the '001 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '001 patent does not contain a written description sufficient to be in possession of separate scanners as required to “acquire image data” and “direct a pulsed laser treatment beam” by at least claim 1 of the '001 patent. Nor does the specification of the '001 patent contain a written description sufficient to be in possession of an imaging system capable of acquiring “image data from locations distributed throughout a volume.”

133. At least claim 1 of the '001 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention.

For instance, the specification of the '001 patent does not contain an enabling description of an imaging system capable of acquiring "image data from locations distributed throughout a volume."

134. At least claim 1 of the '001 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "computer system" of at least claim 1 is indefinite because the specification of the '001 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

135. At least claim 1 of the '001 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '001 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '001 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

136. At least claim 1 of the '001 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '001 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '001 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers

Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

137. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '001 patent.

138. Defendants are entitled to a declaration that one or more claims of the '001 patent are invalid.

139. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XI

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '415 PATENT

140. Defendants repeat and re-allege paragraphs 1-139 as if fully set forth herein.

141. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '415 patent.

142. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '415 patent.

143. LenSx® does not meet each and every limitation of claim 1 of the '415 patent, which claims:

A method for incising ocular tissue during a cataract surgical procedure, the method comprising:

operating an imaging device to acquire image data of ocular tissue, the image data including lens interior image data for an interior portion of the lens of a patient's eye;

processing the image data via a control system so as to generate an anterior capsulotomy scanning pattern for scanning a focal zone of a laser beam for

performing an anterior capsulotomy, the imaging device being operatively coupled to the control system;

generating the laser beam; and

scanning the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is controlled by the control system based on the image data.

144. Defendants do not directly infringe because Defendants do not perform cataract surgery.

145. Claim 1 requires that the "focal zone of [the] laser beam" is based on the processed "image data." LenSx® does not operate the laser beam based on "image data" but requires surgeon input. Ultimately, the surgeon uses images to adjust and verify the position and orientation of the selected surgical patterns.

146. Further, Defendants do not infringe the '415 patent because Defendants do not practice the method disclosed. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '415 patent for the reasons alleged in paragraphs 144-145 above.

Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '415 patent because Defendants do not specifically intend for another party to infringe the '415 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '415 patent. Defendants also have no knowledge of direct infringement of the '415 patent by any third party.

147. Moreover, as explained in paragraphs 144-146, Defendants do not contribute to infringement of the '415 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '415 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '415 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

148. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '415 patent, either literally or under the doctrine of equivalents.

149. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '415 PATENT

150. Defendants repeat and re-allege paragraphs 1-149 as if fully set forth herein.

151. Defendants allege that the claims of the '415 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

152. At least claim 1 of the '415 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '415 patent does not contain a written description sufficient to

be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '415 patent.

153. At least claim 1 of the '415 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '415 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

154. At least claim 1 of the '415 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '415 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '415 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

155. At least claim 1 of the '415 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in

claim 1 of the '415 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '415 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

156. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '415 patent.

157. Defendants are entitled to a declaration that one or more claims of the '415 patent are invalid.

158. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XIII

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '448 PATENT

159. Defendants repeat and re-allege paragraphs 1-158 as if fully set forth herein.

160. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '448 patent.

161. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '448 patent.

162. LenSx® does not meet each and every limitation of claim 1 of the '448 patent, which claims:

A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular issue, and an imaging device; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for ocular tissue of a patient's eye, the image data including lens interior image data for an interior portion of the lens of the patient's eye;

process the image data to determine an anterior capsulotomy scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsulotomy; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data.

163. The "control system" of claim 1 must be "configured to" "operate the imaging device," "process the image data," and "operate the laser and the scanning assembly" and must be limited to the disclosed embodiments in the specification. The '448 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

164. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '448 patent for the reasons alleged in paragraph 163 above. Defendants also do not induce or contribute

to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '448 patent because Defendants do not specifically intend for another party to infringe the '448 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '448 patent. Defendants also have no knowledge of direct infringement of the '448 patent by any third party.

165. Moreover, as explained in paragraphs 163-164, Defendants do not contribute to infringement of the '448 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '448 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '448 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

166. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the

component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

167. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '448 patent, either literally or under the doctrine of equivalents.

168. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XIV

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '448 PATENT

169. Defendants repeat and re-allege paragraphs 1-168 as if fully set forth herein.

170. Defendants allege that the claims of the '448 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

171. At least claim 1 of the '448 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the

specification of the '448 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '448 patent.

172. At least claim 1 of the '448 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '448 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

173. At least claim 1 of the '448 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '448 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '448 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

174. At least claim 1 of the '448 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '448 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '448 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers

Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

175. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '448 patent.

176. Defendants are entitled to a declaration that one or more claims of the '448 patent are invalid.

177. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XV

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '732 PATENT

178. Defendants repeat and re-allege paragraphs 1-177 as if fully set forth herein.

179. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '732 patent.

180. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '732 patent.

181. LenSx® does not meet each and every limitation of claim 1 of the '732 patent, which claims:

A laser surgical system for making incisions in ocular tissue during a cataract surgical procedure, the system comprising:

a laser operable to generate a laser beam for incising ocular tissue;

a scanning assembly operable to direct a focal zone of the laser beam to locations within a patient's eye;

an optical coherence tomography (OCT) imaging device; and

a control system operably coupled to the laser, the scanning assembly, and the OCT imaging device; the control system being configured to:

operate the OCT imaging device to generate image data for ocular tissue of the patient, the image data including lens interior image data for an interior portion of the lens of the patient's eye;

process the image data to determine an anterior capsulotomy scanning pattern for scanning the focal zone of the laser beam for performing an anterior capsulotomy; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsulotomy scanning pattern so as to perform the anterior capsulotomy, wherein positioning of the focal zone is guided by the control system based on the image data.

182. The "control system" of claim 1 must be "configured to" "operate the OCT imaging device," "process the image data," and "operate the laser and the scanning assembly" and must be limited to the disclosed embodiments in the specification. The '732 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical

scanning system, but instead contains separate scanning systems for the laser and OCT.

183. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '732 patent for the reasons alleged in paragraph 182 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '732 patent because Defendants do not specifically intend for another party to infringe the '732 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '732 patent. Defendants also have no knowledge of direct infringement of the '732 patent by any third party.

184. Moreover, as explained in paragraphs 182-183, Defendants do not contribute to infringement of the '732 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '732 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a

component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '732 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

185. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted

for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

186. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '732 patent, either literally or under the doctrine of equivalents.

187. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XVI

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '732 PATENT

188. Defendants repeat and re-allege paragraphs 1-187 as if fully set forth herein.

189. Defendants allege that the claims of the '732 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

190. At least claim 1 of the '732 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '732 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '732 patent.

191. At least claim 1 of the '732 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '732 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

192. At least claim 1 of the '732 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '732 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '732 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al.,

published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

193. At least claim 1 of the '732 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '732 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '732 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at

1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

194. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '732 patent.

195. Defendants are entitled to a declaration that one or more claims of the '732 patent are invalid.

196. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XVII

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '725 PATENT

197. Defendants repeat and re-allege paragraphs 1-196 as if fully set forth herein.

198. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '725 patent.

199. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '725 patent.

200. LenSx® does not meet each and every limitation of claim 1 of the '725 patent, which claims:

A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire point by point image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for patient's crystalline lens;

process the image data to identify a location for each of one or more targets in the lens of the patient;

process the image data to determine a treatment scanning pattern for scanning a focal zone of the laser beam for performing one or more incisions in the lens capsule; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the treatment scanning pattern at each location of the one or more targets, wherein positioning of the focal zone is guided by the control system based on the location of the one or more targets so as to perform the one or more incision in the lens capsule.

201. LenSx® does not have “an imaging device” capable of “acquir[ing] point by point image data from locations distributed throughout a volume” of the

lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

202. Further, the “control system” of claim 1 must be “configured to” “operate the imaging device,” “process the image data,” and “operate the laser and the scanning assembly” and must be limited to the disclosed embodiments in the specification. The ’725 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

203. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’725 patent for the reasons alleged in paragraphs 201-202 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’725 patent because Defendants do not specifically intend for another party to infringe the ’725 patent and do not know that the other party’s acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to

directly infringe any claim of the '725 patent. Defendants also have no knowledge of direct infringement of the '725 patent by any third party.

204. Moreover, as explained in paragraphs 201-203, Defendants do not contribute to infringement of the '725 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '725 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '725 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

205. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not

supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

206. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '725 patent, either literally or under the doctrine of equivalents.

207. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XVIII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '725 PATENT

208. Defendants repeat and re-allege paragraphs 1-207 as if fully set forth herein.

209. Defendants allege that the claims of the '725 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

210. At least claim 1 of the '725 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '725 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '725 patent. Nor does the specification of the '725 patent contain a written description sufficient to be in possession of an imaging device capable of acquiring "image data from locations distributed throughout a volume."

211. At least claim 1 of the '725 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention.

For instance, the specification of the '725 patent does not contain an enabling description of an imaging device capable of acquiring "image data from locations distributed throughout a volume."

212. At least claim 1 of the '725 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '725 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

213. At least claim 1 of the '725 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '725 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '725 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

214. At least claim 1 of the '725 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '725 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '725 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers

Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

215. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '725 patent.

216. Defendants are entitled to a declaration that one or more claims of the '725 patent are invalid.

217. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XIX

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '648 PATENT

218. Defendants repeat and re-allege paragraphs 1-217 as if fully set forth herein.

219. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '648 patent.

220. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '648 patent.

221. LenSx® does not meet each and every limitation of claim 1 of the '648 patent, which claims:

A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly;

a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data of at least a portion of the lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data for the patient's crystalline lens;

process the image data to determine an anterior capsule incision scanning pattern for scanning a focal zone of the laser beam for performing an anterior capsule incision; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the anterior capsule incision scanning pattern to perform the anterior capsule incision, wherein positioning of the focal zone is determined in part by the control system based on the image data.

222. The "control system" of claim 1 must be "configured to" "operate the imaging device," "process the image data," and "operate the laser and the scanning assembly" and must be limited to the disclosed embodiments in the specification. The '648 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

223. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '648 patent for the reasons alleged in paragraph 222 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '648 patent because Defendants do not specifically intend for another party to infringe the '648 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '648 patent. Defendants also have no knowledge of direct infringement of the '648 patent by any third party.

224. Moreover, as explained in paragraphs 222-223, Defendants do not contribute to infringement of the '648 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '648 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of

the '648 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

225. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such

component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

226. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '648 patent, either literally or under the doctrine of equivalents.

227. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XX

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '648 PATENT

228. Defendants repeat and re-allege paragraphs 1-227 as if fully set forth herein.

229. Defendants allege that the claims of the '648 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112, or other judicially-created bases for invalidity.

230. At least claim 1 of the '648 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process

of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '648 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '648 patent.

231. At least claim 1 of the '648 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "control system" of at least claim 1 is indefinite because the specification of the '648 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

232. At least claim 1 of the '648 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '648 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '648 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24,

1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

233. At least claim 1 of the '648 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '648 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '648 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902

(1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

234. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '648 patent.

235. Defendants are entitled to a declaration that one or more claims of the '648 patent are invalid.

236. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXI

**DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '903
PATENT**

237. Defendants repeat and re-allege paragraphs 1-236 as if fully set forth herein.

238. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '903 patent.

239. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '903 patent.

240. LenSx® does not meet each and every limitation of claim 1 of the '903 patent, which claims:

A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of the one or more tissue structures of the crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries, the lens fragmentation treatment region comprising a posterior cutting boundary located anterior to the posterior capsule of the lens;

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation pattern comprising a scanning pattern at a plurality of depths within the lens fragmentation treatment region; and

operate the laser and the scanning assembly to scan the focal zone of the laser beam in the lens fragmentation

scanning pattern consecutively at each of the plurality of depths within the lens fragmentation treatment region,

wherein positioning of the focal zone is guided by the control system based on the image data.

241. LenSx® does not have “an imaging device” capable of “acquir[ing] image data from locations distributed throughout a volume” of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

242. Further, the “control system” of claim 1 must be “configured to” “operate the imaging device,” “process the image data,” and “operate the laser and the scanning assembly” and must be limited to the disclosed embodiments in the specification. The ’903 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

243. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’903 patent for the reasons alleged in paragraphs 241-242 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’903 patent because Defendants do not specifically intend for another party to infringe the ’903 patent and do not know that the other party’s acts constitute

infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '903 patent. Defendants also have no knowledge of direct infringement of the '903 patent by any third party.

244. Moreover, as explained in paragraphs 241-243, Defendants do not contribute to infringement of the '903 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '903 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '903 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

245. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures all components of LenSx® in the United States and combines those components to

assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

246. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or

indirectly, any valid and enforceable claim of the '903 patent, either literally or under the doctrine of equivalents.

247. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '903 PATENT

248. Defendants repeat and re-allege paragraphs 1-247 as if fully set forth herein.

249. Defendants allege that the claims of the '903 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

250. At least claim 1 of the '903 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '903 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '903 patent. Nor does the specification of the '903 patent contain a written description sufficient to be in possession of an imaging

device capable of acquiring “image data from locations distributed throughout a volume.”

251. At least claim 1 of the ’903 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention. For instance, the specification of the ’903 patent does not contain an enabling description of an imaging device capable of acquiring “image data from locations distributed throughout a volume.”

252. At least claim 1 of the ’903 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required “control system” of at least claim 1 is indefinite because the specification of the ’903 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

253. At least claim 1 of the ’903 patent is invalid as anticipated by the prior art because all elements of claim 1 of the ’903 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the ’903 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published

September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

254. At least claim 1 of the '903 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '903 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '903 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond

Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

255. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '903 patent.

256. Defendants are entitled to a declaration that one or more claims of the '903 patent are invalid.

257. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXIII

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '904 PATENT

258. Defendants repeat and re-allege paragraphs 1-257 as if fully set forth herein.

259. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '904 patent.

260. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '904 patent.

261. LenSx® does not meet each and every limitation of claim 1 of the '904 patent, which claims:

A laser surgical system for making incisions in ocular tissues during a cataract surgical procedure, the system comprising:

a laser system comprising a scanning assembly, a laser operable to generate a laser beam configured to incise ocular tissue;

an imaging device configured to acquire image data from locations distributed throughout a volume of a crystalline lens of the patient and construct one or more images of the patient's eye tissues from the image data, wherein the one or more images comprise an image of at least a portion of the crystalline lens; and

a control system operably coupled to the laser system and configured to:

operate the imaging device to generate image data of a continuous depth profile of the volume of the patient's crystalline lens;

identify one or more boundaries of the crystalline lens based at least in part on the image data;

process the image data to determine a lens fragmentation scanning pattern for scanning a focal zone of the laser beam for performing lens fragmentation, the lens fragmentation scanning pattern comprising a planar pattern at a first depth and at one or more additional depths anterior to the first depth;

process the image data to determine a lens fragmentation treatment region of the lens of the eye based at least in part upon the one or more boundaries;

operate the laser and the scanning assembly to scan the focal zone of the laser beam within the lens fragmentation

treatment region in the planar pattern at the first depth and to subsequently direct the focal zone of the laser beam at the one or more additional depths anterior to the first depth, thereby effecting patterned laser cutting of lens tissue,

wherein positioning of the focal zone is guided by the control system based on the image data.

262. LenSx® does not have “an imaging device” capable of “acquir[ing] image data from locations distributed throughout a volume” of the lens. Instead, LenSx® uses a proprietary OCT system that performs 2-D circle and line scans.

263. Further, the “control system” of claim 1 must be “configured to” “operate the imaging device,” “process the image data,” and “operate the laser and the scanning assembly” and must be limited to the disclosed embodiments in the specification. The ’904 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

264. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’904 patent for the reasons alleged in paragraphs 262-263 above. Defendants also do not induce or contribute to infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’904 patent because Defendants do not specifically intend for another party to

infringe the '904 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '904 patent. Defendants also have no knowledge of direct infringement of the '904 patent by any third party.

265. Moreover, as explained in paragraphs 262-264, Defendants do not contribute to infringement of the '904 patent. Contributory infringement cannot exist without direct infringement. Defendants do not contribute to infringement of the '904 patent because Defendants have not sold, offered to sell, or imported into the United States, and do not sell, offer to sell, or import into the United States, a component, or a material or apparatus, that constitutes a material part of the invention, knowing that it is especially made or adapted for use in infringement of the '904 patent and that it is not a staple article of commerce that has no substantial noninfringing uses. Defendants also have no knowledge of any infringing use of any component or material or apparatus by a third party.

266. Defendants also do not infringe under 35 U.S.C. § 271(f). Defendants do not supply or cause to be supplied components of LenSx® or any other patented machine for combination outside of the United States. Alcon Research manufactures

all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. With respect to § 271(f)(1), Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States. With respect to § 271(f)(2), Defendants do not supply or cause to be supplied in or from the United States any component of LenSx® or any other patented invention that is especially made or especially adapted for use in the invention and is not a staple article of commerce suitable for substantial noninfringing uses. Defendants do not supply or cause to be supplied any such component that is uncombined in whole or in part knowing that the component is especially made or especially adapted for use in the invention and intending that the component will be combined outside of the United States in a way that would infringe if the combination occurred inside the United States.

267. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or

indirectly, any valid and enforceable claim of the '904 patent, either literally or under the doctrine of equivalents.

268. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXIV

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '904 PATENT

269. Defendants repeat and re-allege paragraphs 1-268 as if fully set forth herein.

270. Defendants allege that the claims of the '904 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

271. At least claim 1 of the '904 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '904 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '904 patent. Nor does the specification of the '904 patent contain a written description sufficient to be in possession of an imaging

device capable of acquiring “image data from locations distributed throughout a volume.”

272. At least claim 1 of the ’904 patent is invalid because the specification does not enable a person of skill in the art to make and use the claimed invention. For instance, the specification of the ’904 patent does not contain an enabling description of an imaging device capable of acquiring “image data from locations distributed throughout a volume.”

273. At least claim 1 of the ’904 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required “control system” of at least claim 1 is indefinite because the specification of the ’904 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

274. At least claim 1 of the ’904 patent is invalid as anticipated by the prior art because all elements of claim 1 of the ’904 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the ’904 patent is anticipated by at least U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published

September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

275. At least claim 1 of the '904 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '904 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '904 patent is rendered obvious by at least U.S. Patent No. 6,004,314 to Wei et al. published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004; Joseph Izatt et al., *Micrometer-Scale Resolution Imaging of the Anterior Eye In Vivo With Optical Coherence Tomography*, 112(12) Arch. Ophthalmol., 1584 (1994); Reginald Birngruber et al., *Femtosecond laser-tissue interactions: Retinal injury studies*, IEEE J. Quantum Electron, vol. QE-23, at 1836 (1987); Tibor Juhasz et al., Corneal Refractive Surgery with Femtosecond

Lasers, IEEE J. of Selected Topics in Quantum Electronics, Vo. 5, No. 4, 902, 902 (1999); and Ronald M. Kurtz, *Ultrafast Lasers in Ophthalmology*, Ultrafast Lasers Technology and Applications, 745, 746 (2003), either alone, combined together, or combined with other prior art.

276. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '904 patent.

277. Defendants are entitled to a declaration that one or more claims of the '904 patent are invalid.

278. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXV

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '023 PATENT

279. Defendants repeat and re-allege paragraphs 1-278 as if fully set forth herein.

280. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '023 patent.

281. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '023 patent.

282. LenSx® does not meet each and every limitation of claim 1 of the '023 patent, which recites:

A cataract surgery scanning system for treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye, comprising:

a treatment light source for generating a treatment light beam;

a scanner for deflecting the light beam to form first and second treatment patterns of the treatment light beam under the control of a controller; and

a delivery system comprising the controller operatively coupled to the treatment light source and the scanner, and programmed to: (i) deliver the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision therein that provides access to an eye chamber of the patient's eye, the incision to be formed by delivering the first treatment pattern only partially extending through the target tissue, and (ii) deliver the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue, or along corneal tissue-of the patient's eye.

283. The "cataract surgery scanning system" of claim 1 of the '023 patent comprises of "a scanner." LenSx® does not comprise of "a scanner" because the LenSx® requires two, separate scanning systems for the laser and OCT.

284. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '023 patent for the reasons alleged in paragraph 283 above. Defendants also do not induce infringement. Induced infringement cannot exist without direct infringement.

Defendants do not induce and have not induced infringement of the '023 patent because Defendants do not specifically intend for another party to infringe the '023 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '023 patent. Defendants also have no knowledge of direct infringement of the '023 patent by any third party.

285. Defendants also do not infringe under 35 U.S.C. § 271(f)(1). Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. Defendants do not actively induce the combination of such components abroad in a manner that would infringe

if the combination occurred in the United States for similar reasons to those explained in paragraphs 283-284.

286. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '023 patent, either literally or under the doctrine of equivalents.

287. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXVI

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '023 PATENT

288. Defendants repeat and re-allege paragraphs 1-287 as if fully set forth herein.

289. Defendants allege that the claims of the '023 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

290. At least claim 1 of the '023 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the

specification for the '023 patent does not contain a written description sufficient to be in possession of a single scanner capable of delivering both treatment patterns as required by at least claim 1 of the '023 patent.

291. At least claim 1 of the '023 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "controller" of at least claim 1 is indefinite because the specification of the '023 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

292. At least claim 1 of the '023 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '023 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '023 patent is anticipated by at least the '084 patent published August 31, 2006, U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

293. At least claim 1 of the '023 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '023 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '023 patent is rendered obvious by at least K. Budak et al., *Limbal relaxing incisions with cataract surgery*, J. Cataract Refract. Surg. 1998; 24:503-508; H. Bayramlar et al., *Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery*, J. Cataract Refract. Surg. 2003; 29:723-728; L. Wang et al., *Peripheral corneal relaxing incisions combined with cataract surgery*, J. Cataract Refract. Surg. 2003; 29:712-722; Louis D. Nichamin, *Treating astigmatism at the time of cataract surgery*, Curr. Opin. Ophthalmol. 2003, 14:35-38; U.S. Pat. No. 2005/0241653 to Van Heugten et al.; U.S. Patent No. 5,549,632 to Lai; U.S. Patent No. 6,325,792 to Swinger et al., either alone, combined together, or combined with other prior art.

294. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '023 patent.

295. Defendants are entitled to a declaration that one or more claims of the '023 patent are invalid.

296. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXVII

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '024 PATENT

297. Defendants repeat and re-allege paragraphs 1-296 as if fully set forth herein.

298. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '024 patent.

299. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '024 patent.

300. LenSx® does not meet each and every limitation of claim 1 of the '024 patent, which recites:

A cataract surgery method of treating target tissue in one or more of a cornea, limbus or sclera of a patient's eye, comprising:

generating a treatment light beam;

deflecting the treatment light beam using a scanner to form first and second treatment patterns;

delivering the first treatment pattern to a first target tissue selected from the group consisting of the cornea, limbus and sclera of the patient's eye to form a cataract incision

that is sized to provide access to an eye chamber of the patient's eye for lens removal instrumentation; and

delivering the second treatment pattern to a second target tissue to form a relaxation incision along or near limbus tissue or along corneal tissue anterior to the limbus tissue of the patient's eye to reduce astigmatism thereof,

wherein the incision formed by delivering the first treatment pattern only partially extends through the target tissue.

301. The "cataract surgery method" of claim 1 of the '024 patent comprises using "a scanner" to form first and second treatment patterns. LenSx® does not comprise of "a scanner" because the LenSx® requires two, separate scanning systems for the laser and OCT.

302. Defendants also do not infringe the '024 patent because Defendants do not practice the method disclosed. At a minimum, and without limitation, Defendants do not directly infringe any asserted claim of the '024 patent for the reasons alleged in paragraph 301 above. Defendants also do not induce infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '024 patent because Defendants do not specifically intend for another party to infringe the '024 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge,

or encourage, ophthalmologists or other third parties to directly infringe any claim of the '024 patent. At least claim 1 of the '024 patent requires "a cataract surgery method" in which a relaxation incision is formed but LenSx® does not require a relaxation incision be performed during cataract surgery. Further, at least claim 1 of the '024 patent requires the first treatment pattern to "only partially extend[] through the target tissue," but LenSx® may create corneal incisions that are not of partial depth through target tissue. Defendants also have no knowledge of direct infringement of the '024 patent by any third party.

303. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '024 patent, either literally or under the doctrine of equivalents.

304. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXVIII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '024 PATENT

305. Defendants repeat and re-allege paragraphs 1-304 as if fully set forth herein.

306. Defendants allege that the claims of the '024 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

307. At least claim 1 of the '024 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '024 patent does not contain a written description sufficient to be in possession of a single scanner capable of delivering both treatment patterns as required by at least claim 1 of the '024 patent.

308. At least claim 1 of the '024 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '024 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '024 patent is anticipated by at least the '084 patent published August 31, 2006, U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No.

5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

309. At least claim 1 of the '024 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '024 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '024 patent is rendered obvious by at least K. Budak et al., *Limbal relaxing incisions with cataract surgery*, J. Cataract Refract. Surg. 1998; 24:503-508; H. Bayramlar et al., *Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery*, J. Cataract Refract. Surg. 2003; 29:723-728; L. Wang et al., *Peripheral corneal relaxing incisions combined with cataract surgery*, J. Cataract Refract. Surg. 2003; 29:712-722; Louis D. Nichamin, *Treating astigmatism at the time of cataract surgery*, Curr. Opin. Ophthalmol. 2003, 14:35-38; U.S. Pat. Pub. No. 2005/0241653 to Van Heugten et al.; U.S. Patent No. 5,549,632 to Lai; U.S. Patent No. 6,325,792 to Swinger et al., either alone, combined together, or combined with other prior art.

310. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '024 patent.

311. Defendants are entitled to a declaration that one or more claims of the '024 patent are invalid.

312. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXIX

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '356 PATENT

313. Defendants repeat and re-allege paragraphs 1-312 as if fully set forth herein.

314. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '356 patent.

315. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '356 patent.

316. LenSx® does not meet each and every limitation of claim 1 of the '356 patent, which recites:

An optical beam scanning system for incising target tissue in a patient's eye, the optical beam scanning system comprising:

a laser source configured to deliver a laser beam comprising a plurality of laser pulses, the laser beam being configured to produce optical breakdown and initiate a

plasma-mediated process within the target tissue at a focal spot of the laser beam;

an Optical Coherence Tomography (OCT) imaging device configured to generate signals that can be used to create an image of eye tissue that includes the cornea of the patient's eye;

a delivery system for delivering the laser beam to the target tissue to form a cataract incision;

a scanner operable to scan the focal spot of the laser beam to different locations within the patient's eye; and

a controller operatively coupled to the laser source, the OCT imaging device and the scanner, the optical beam scanning [sic], the controller programmed to:

scan the eye tissue with the OCT device to generate imaging data for the target tissue that includes imaging data for the cornea;

generate an incision pattern based at least in part on the imaging data, the incision pattern forming one or more relaxation incisions into the cornea, wherein each of the relaxation incision extends in an angular direction for a predetermined length less than a full circle, and wherein at least one of the one or more relaxation incisions is a partially penetrating incision that leaves an un-incised tissue thickness; and

scan the focal spot of the laser beam in the incision pattern, wherein the focal spot of the laser beam is guided based on the imaging data so that the focal spot of the laser beam is scanned from a posterior portion of the eye and proceeding anteriorly.

317. The "Optical Coherence Tomography (OCT) imaging device" of claim

1 of the '356 patent must be "configured to" generate signals and must be limited to the disclosed embodiments in the specification. The '356 specification discloses an

optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

318. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the '356 patent for the reasons alleged in paragraph 317 above. Defendants also do not induce infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the '356 patent because Defendants do not specifically intend for another party to infringe the '356 patent and do not know that the other party's acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the '356 patent. Defendants also have no knowledge of direct infringement of the '356 patent by any third party.

319. Defendants also do not infringe under 35 U.S.C. § 271(f)(1). Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Alcon Research

manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States for similar reasons to those explained in paragraphs 317-318.

320. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '356 patent, either literally or under the doctrine of equivalents.

321. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXX

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '356 PATENT

322. Defendants repeat and re-allege paragraphs 1-321 as if fully set forth herein.

323. Defendants allege that the claims of the '356 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

324. At least claim 1 of the '356 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '356 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and imaging device as required by at least claim 1 of the '356 patent.

325. At least claim 1 of the '356 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "controller" of at least claim 1 is indefinite because the specification of the '356 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

326. At least claim 1 of the '356 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '356 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a

printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '356 patent is anticipated by at least the '084 patent published August 31, 2006, U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

327. At least claim 1 of the '356 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '356 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '356 patent is rendered obvious by at least K. Budak et al., *Limbal relaxing incisions with cataract surgery*, J. Cataract Refract. Surg. 1998; 24:503-508; H. Bayramlar et al., *Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery*, J. Cataract Refract. Surg. 2003; 29:723-728; L. Wang et al., *Peripheral corneal relaxing incisions combined*

with cataract surgery, J. Cataract Refract. Surg. 2003; 29:712-722; Louis D. Nichamin, *Treating astigmatism at the time of cataract surgery*, Curr. Opin. Ophthalmol. 2003, 14:35-38; U.S. Pat. Pu. No. 2005/0241653 to Van Heugten et al.; U.S. Patent No. 5,549,632 to Lai; U.S. Patent No. 6,325,792 to Swinger et al., either alone, combined together, or combined with other prior art.

328. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '356 patent.

329. Defendants are entitled to a declaration that one or more claims of the '356 patent are invalid.

330. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXXI

DECLARATORY JUDGEMENT OF NONINFRINGEMENT OF THE '548 PATENT

331. Defendants repeat and re-allege paragraphs 1-330 as if fully set forth herein.

332. Plaintiffs has brought claims against Defendants alleging infringement of at least claim 1 of the '548 patent.

333. A real, immediate, and justiciable controversy exists between Plaintiffs and Defendants regarding Defendants' alleged infringement of the '548 patent.

334. LenSx® does not meet each and every limitation of claim 1 of the '548 patent, which recites:

A scanning system for treating target tissue in a patient's eye, comprising:

- a) an ultrafast laser source configured to deliver a laser beam comprising a plurality of laser pulses;
- b) an Optical Coherence Tomography (OCT) device configured to generate signals which may be used to create an image of the cornea and limbus of the eye of the patient;
- c) a scanner configured to focus and direct the laser beam in a pattern within the cornea or limbus to create incisions therein; and
- d) a controller operatively coupled to the laser source and scanner programmed to determine a treatment pattern based upon the signals from the OCT device, the treatment pattern forming a cataract incision in the cornea that provides access for lens removal instrumentation to a crystalline lens of the patient's eye and one or more relaxation incisions in the cornea or limbus, wherein the cataract incision has an arcuate extent of less than 360 degrees in a top view, wherein the cataract incision includes a bevel shape in a cross-sectional view, the bevel shape including a first segment and a second segment which intersect each other at an angle, the cataract incision being entirely located in the cornea and intersecting both an anterior surface and a posterior surface of the cornea, and to control the scanner to scan the position of the laser beam in the treatment pattern.

335. The "Optical Coherence Tomography (OCT) device" of claim 1 of the '548 patent must be "configured to" generate signals and must be limited to the

disclosed embodiments in the specification. Similarly, the “scanner” of claim 1 of the ’548 patent must be “configured to” focus and direct the laser and must be limited to the disclosed embodiments in the specification. The ’548 specification discloses an optical scanning system that is shared between the laser and OCT. LenSx® does not contain a shared optical scanning system, but instead contains separate scanning systems for the laser and OCT.

336. At a minimum, and without limitation, Defendants and their customers using LenSx® do not directly infringe any asserted claim of the ’548 patent for the reasons alleged in paragraph 335 above. Defendants also do not induce infringement. Induced infringement cannot exist without direct infringement. Defendants do not induce and have not induced infringement of the ’497 patent because Defendants do not specifically intend for another party to infringe the ’497 patent and do not know that the other party’s acts constitute infringement. Defendants have not taken any affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement. For example, Defendants have not caused, urged, or encouraged, and do not actively cause, urge, or encourage, ophthalmologists or other third parties to directly infringe any claim of the ’497 patent. Defendants also have no knowledge of direct infringement of the ’497 patent by any third party.

337. Moreover, as explained in paragraphs 335-336, Defendants also do not infringe under 35 U.S.C. § 271(f)(1). Defendants do not supply or cause to be supplied in or from the United States all or a substantial portion of the components of LenSx® or any other patented machine, where the components are uncombined in whole or in part. Alcon Research manufactures all components of LenSx® in the United States and combines those components to assemble LenSx® entirely within the United States. No such combinations occur outside of the United States. Defendants also manufacture the LenSx® SoftFit Patient Interface entirely within the United States, and it is sold as an accessory to, not as a component of, the LenSx®. Defendants do not actively induce the combination of such components abroad in a manner that would infringe if the combination occurred in the United States for similar reasons to those explained in paragraph 335-336.

338. Defendants are entitled to a declaratory judgment that Defendants do not infringe, either directly or indirectly, and have not infringed, either directly or indirectly, any valid and enforceable claim of the '548 patent, either literally or under the doctrine of equivalents.

339. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT XXXII

DECLARATORY JUDGEMENT OF INVALIDITY OF THE '548 PATENT

340. Defendants repeat and re-allege paragraphs 1-339 as if fully set forth herein.

341. Defendants allege that the claims of the '548 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 102, 103, and/or 112.

342. At least claim 1 of the '548 patent is invalid because the patent does not contain a written description of the claimed invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to demonstrate to a person of skill in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein. For instance, the specification of the '548 patent does not contain a written description sufficient to be in possession of separate scanners for the laser beam and OCT device as required by at least claim 1 of the '548 patent.

343. At least claim 1 of the '548 patent is invalid because the claim does not particularly point out and distinctly claim the subject matter which the applicant regards as his invention. For instance, the required "controller" of at least claim 1 is indefinite because the specification of the '548 patent does not disclose an algorithm that is clearly linked to the claimed functionality.

344. At least claim 1 of the '548 patent is invalid as anticipated by the prior art because all elements of claim 1 of the '548 patent were known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant, or patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application. For instance, claim 1 of the '548 patent is anticipated by at least the '084 patent published August 31, 2006, U.S. Patent No. 6,004,314 to Wei et al., published December 21, 1999; U.S. Patent No. 6,454,761 to Freedman, published September 24, 2002; U.S. Patent No. 5,098,426 to Sklar et al., published March 24, 1992; U.S. Patent No. 6,482,199 to Neev, published November 19, 2002; and U.S. Patent No. 6,787,733 to Lubatschowski et al., published September 7, 2004.

345. At least claim 1 of the '548 patent is invalid as obvious in view of the prior art because, at the least, any differences between the subject matter claimed in claim 1 of the '548 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. A person having ordinary skill in the relevant art would have had reason to combine the teachings of the prior art to achieve the claimed invention and would have had a reasonable expectation of success in doing so. For instance, claim 1 of the '548 patent is rendered obvious by at least K. Budak

et al., *Limbal relaxing incisions with cataract surgery*, J. Cataract Refract. Surg. 1998; 24:503-508; H. Bayramlar et al., *Limbal relaxing incisions for primary mixed astigmatism and mixed astigmatism after cataract surgery*, J. Cataract Refract. Surg. 2003; 29:723-728; L. Wang et al., *Peripheral corneal relaxing incisions combined with cataract surgery*, J. Cataract Refract. Surg. 2003; 29:712-722; Louis D. Nichamin, *Treating astigmatism at the time of cataract surgery*, Curr. Opin. Ophthalmol. 2003, 14:35-38; U.S. Pat. Pu. No. 2005/0241653 to Van Heugten et al.; U.S. Patent No. 5,549,632 to Lai; U.S. Patent No. 6,325,792 to Swinger et al., either alone, combined together, or combined with other prior art.

346. A present, genuine, and justiciable controversy exists between Defendants and Plaintiffs regarding, *inter alia*, the validity of the claims of the '548 Patent.

347. Defendants are entitled to a declaration that one or more claims of the '548 patent are invalid.

348. This is an exceptional case entitling Defendants to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Alcon hereby respectfully requests a jury trial on all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, for its Answer and Declaratory Judgment Counterclaims, Alcon requests the following judgments and relief against AMO:

- (i) That all claims against Defendants be dismissed with prejudice and that all relief requested by Plaintiffs be denied;
- (ii) That a judgment be entered declaring that Defendants have not infringed and do not infringe, either directly or indirectly, any valid and enforceable claim of the AMO Asserted Patents, either literally or under the doctrine of equivalents;
- (iii) That a judgment be entered declaring that the claims of the AMO Asserted Patents are invalid and/or unenforceable for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 102, 103, and/or 112;
- (iv) An award of Alcon's costs as the prevailing party;
- (v) That a judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285, and accordingly that Defendants are entitled to recover reasonable attorneys' fees and costs upon prevailing in this action; and
- (vi) That Defendants be awarded such other relief that the Court deems just and equitable, or which the Court deems just and proper.

ALCON'S PATENT COUNTERCLAIMS

Alcon Inc., Alcon Research, LLC and Alcon Vision, LLC (collectively, the “Alcon Patent Plaintiffs”) demand a trial by jury on all issues so triable and assert the following counterclaims against Counterclaim-Defendants AMO Development, LLC, AMO Manufacturing USA, LLC, AMO Sales and Service, Inc., and Johnson & Johnson Surgical Vision, Inc. (collectively, “AMO Accused Infringers”):

PARTIES

349. Alcon Inc. is a Swiss corporation with a principal place of business at Rue Louis-d’Affry 6, 1701 Fribourg, Switzerland.

350. Alcon Research, LLC (“Alcon Research”) is a Delaware company with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

351. Alcon Vision, LLC (“Alcon Vision”) is a Delaware company with a principal place of business at 6201 South Freeway, Fort Worth, Texas.

352. Upon information and belief, AMO Development, LLC (“AMO Development”) is a Delaware company with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. AMO Development is an indirect subsidiary of Johnson & Johnson Surgical Vision, Inc. (“JJSV”).

353. Upon information and belief, AMO Manufacturing USA, LLC (“AMO Manufacturing”) is a Delaware company with a principal place of business at 510

Cottonwood Drive, Milpitas, California. AMO Manufacturing is an indirect subsidiary of JJSV.

354. Upon information and belief, AMO Sales and Service, Inc. (“AMO Sales and Service”) is a Delaware corporation with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. AMO Sales and Service is an indirect subsidiary of JJSV.

355. Upon information and belief, Johnson & Johnson Surgical Vision, Inc. (“JJSV”) is a Delaware corporation with a principal place of business at 1700 East St. Andrew Place, Santa Ana, California. According to the FDA’s website, JJSV is the owner/operator of AMO Manufacturing, manufacturer of CATALYS®.

JURISDICTION AND VENUE

356. This Court has exclusive subject matter jurisdiction over Alcon Patent Plaintiffs’ patent infringement claims pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338; and the patent laws of the United States, 35 U.S.C. § 1 et seq.

357. This Court has personal jurisdiction over each of AMO Development, AMO Manufacturing USA, and AMO Sales and Service because each has subjected itself to the jurisdiction of this Court by filing their Complaint. Furthermore, AMO Development, AMO Manufacturing, AMO Sales and Service, and JJSV are entities organized and existing under the laws of the State of Delaware.

358. Upon information and belief, AMO Development, AMO Manufacturing, AMO Sales and Service, and JJSV make, use, offer to sell, and/or sell CATALYS® and consumables in the United States, and supply or cause to be supplied CATALYS® and consumables from the United States for use abroad. Upon information and belief, AMO Development, AMO Manufacturing, AMO Sales and Service, and JJSV have committed acts of patent infringement in Delaware.

359. Upon information and belief, AMO Development researches and develops improvements to CATALYS®. Upon information and belief, CATALYS® is manufactured at facilities operated by AMO Manufacturing in the United States and is distributed both domestically and internationally. According to the FDA's website, JJSV is the owner/operator of AMO Manufacturing, manufacturer of CATALYS®. Upon information and belief, CATALYS® is manufactured at facilities operated by JJSV in the United States and distributed both domestically and internationally. Upon information and belief, AMO Sales and Service acts as a distributor for CATALYS® both domestically and internationally, and is responsible for repair and maintenance of CATALYS® systems used by their customers.

360. Upon information and belief, AMO Development, AMO Manufacturing, AMO Sales and Service, and JJSV act as agents of each other and/or

operate in concert as integrated parts of the same business group with respect to CATALYS®.

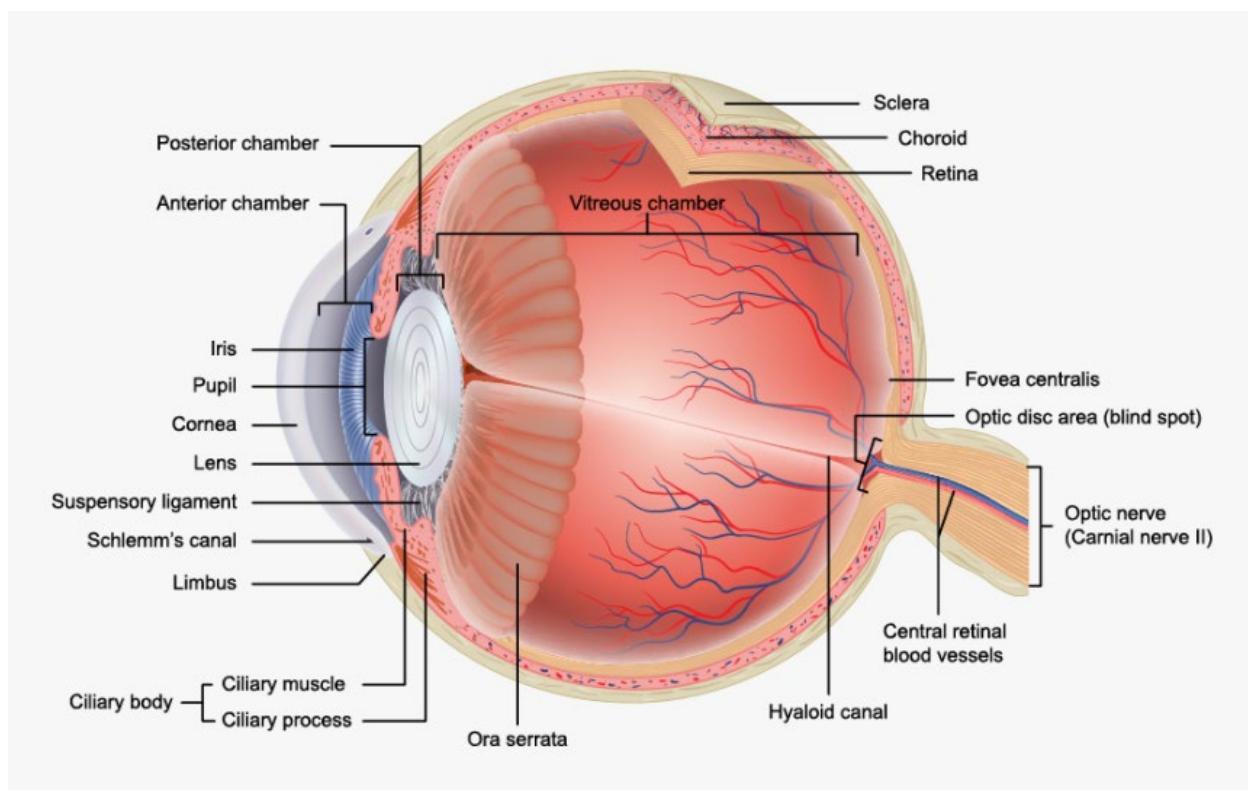
361. Venue in this Court is proper based on the choice of forum by Plaintiffs and pursuant to 28 U.S.C. §§ 1391(b)-(c), and 1400(b).

ALCON PATENT PLAINTIFFS' LENSX® CATARACT SURGERY SYSTEM

362. Alcon Inc. and its affiliated entities are pioneers in the field of cataract surgery systems and lead the industry in the United States and around the world. Cataracts are a condition of the eye that causes blurring vision and, without treatment, leads to blindness. Cataracts are responsible for 51% of the world's blindness, and impact roughly 20 million people. World Health Organization, "Priority Eye Diseases," available at <https://www.who.int/blindness/causes/priority/en/index1.html> (July 20, 2020). LenSx®'s inventors leveraged their deep knowledge of the anatomy of the eye, OCT imaging, and femtosecond laser tissue cutting to develop the first laser system capable of treating this condition.

363. In 2011, Alcon LenSx, Inc. was first to market with the LenSx® Laser System ("LenSx®"), a commercial femtosecond laser system for use in femtosecond laser-assisted cataract surgery ("FLACS"). Alcon LenSx, Inc., its predecessor LenSx Lasers, Inc., and Alcon Research have spent millions researching and developing LenSx®. This cutting-edge system has treated over 1.5 million people, allowing patients to regain clear vision.

364. The standard treatment for cataracts is to replace the natural, clouded lens with a new artificial lens. The lens, however, is deep in the eye—under the cornea and contained within the lens capsule, which is the bag surrounding the lens. To access the lens, an incision is made in the cornea and then an opening is made in the capsule. Once a surgeon accesses the lens, it is broken apart and removed. After the lens is removed, the artificial lens is implanted and the incisions are closed.



365. Before the use of femtosecond lasers, all incisions in the eye were performed manually with a scalpel and an ultrasound probe to break up the lens into smaller pieces for removal.

366. Manual cataract surgery relies on the precision and experience of the physician. In a FLACS procedure, a laser assists with several steps of the cataract

procedure. Instead of a scalpel, a laser can make intricate and precise incisions in the cornea. And the laser can be used to fragment the lens, thereby reducing the amount of time and effort required to remove the cataractous lens. The LenSx® system was the first commercially available FLACS system. LenSx® increases the precision, efficiency, and accuracy of the procedure.

Development of LenSx® Cataract Surgery System

367. LenSx® was invented by Ron Kurtz and Tibor Juhasz, the pioneers of femtosecond lasers and founders of the LenSx Lasers company. Dr. Kurtz earned his B.A. in Biochemistry from Harvard College and his M.D. from the University of California, San Diego. Starting in the early 1990s, Dr. Kurtz began investigating the use of femtosecond lasers as a resident at the University of Michigan. From 1995 to 2000, he was on the retina faculty at the University of Michigan, where he established the Ultrafast Laser Medical Group. Dr. Kurtz then became a Professor of Clinical Ophthalmology at the University of California, Irvine. There, Dr. Kurtz teamed up with Dr. Juhasz, a laser physicist at U.C. Irvine. Dr. Juhasz earned his B.S. and Ph.D. in physics from JATE University of Szeged in Hungary, and has over thirty years of experience in the field of medical applications of lasers.

368. Drs. Kurtz and Juhasz initially developed a femtosecond laser for use in LASIK surgery and co-founded IntraLase. IntraLase was the first femtosecond laser approved for use in creating corneal flaps for refractive surgery such as LASIK.

In 2007, Drs. Kurtz and Juhasz sold IntraLase to Advanced Medical Optics, Inc., a predecessor of the AMO Accused Infringers, which was eventually purchased by JJSV.

369. Drs. Kurtz and Juhasz then focused on commercial applications of femtosecond lasers for cataract surgery. Similar to LASIK, the first step of cataract surgery is to create an incision in the cornea. The primary difference is that in LASIK, a flap is made to expose the interior of the cornea whereas in FLACS an incision is made in the cornea to gain access to the anterior capsule. The other primary difference is that LASIK generally uses direct visualization by the surgeon, as the cornea is clear and the corneal incision is made at a shallow depth.

370. In 2008, Drs. Kurtz and Juhasz founded LenSx Lasers, Inc. and developed LenSx®. LenSx® included concrete improvements over the existing landscape and was built from the ground up. Rather than using preexisting OCT systems and laser engines, LenSx developed both its OCT system and laser engine entirely in-house.

371. In July 2010, LenSx Lasers, Inc. was acquired by Alcon LenSx, Inc., a predecessor of one of the Alcon Patent Plaintiffs, validating the value and interest of the new technology in the ophthalmic marketplace. See

<https://crstoday.com/articles/2011-mar/the-origins-of-laser-cataract-surgery/>.

Alcon evaluated multiple emerging companies in the FLACS space. LenSx Lasers,

Inc. stood out as a possible acquisition in light of the team's depth of experience in ophthalmology and because its innovative technology was closest to market. At the time of acquisition, LenSx Lasers, Inc.'s team of roughly 40 engineers and developers had over ten years of experience in the field of laser ophthalmology, including hardware and software development, commercialization, manufacturing, sales, and technical services.

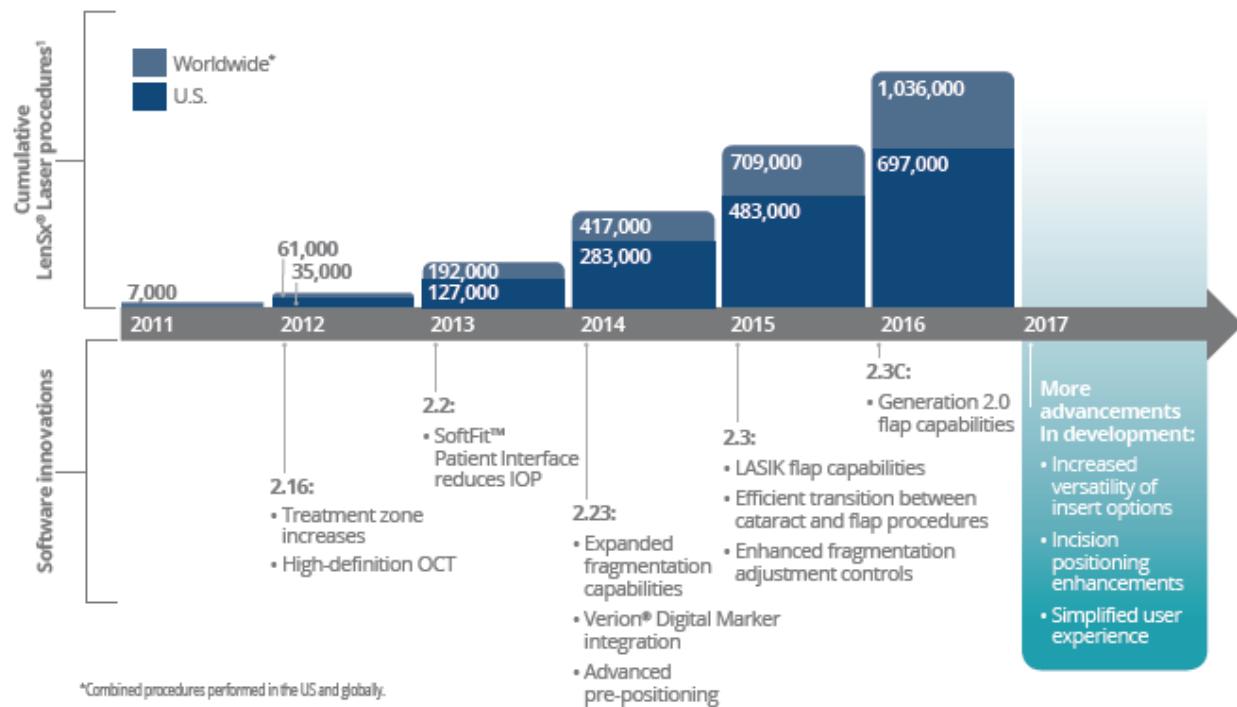
372. The acquisition was fitting: Alcon Inc. is the global leader in eye care. With a 70-plus-year heritage, Alcon Inc. is the largest eye care device company in the world, with complementary businesses in surgical (*e.g.*, surgical equipment, instruments, and devices) and vision care (*e.g.*, contact lenses, contact lens care, and ocular health products). Just like LenSx Lasers, Alcon Inc. focuses on cutting-edge innovation and breakthrough technology that transforms treatment of eye diseases and eye conditions.

373. When LenSx® launched, physicians recognized that it “is the future of cataract surgery” and “it is likely to grow the practice.” Gualdi et al., *Femto-Laser Cataract Surgery*, (2014), ch. 4. (“In the beginning of 2012, the question was ‘Is femtophaco surgery the future of cataract surgery?’ After 1 year of practicing femto laser-assisted cataract surgery with the LenSx® system, my answer is ‘YES! This is the future of cataract surgery.’”); Slade, S. “The LenSx Laser: How the LenSx laser, and laser refractive cataract surgery, impacts the ophthalmic practice,” Innovations

in Ophthalmology 2011, http://bmctoday.net/innovations2011/digital_supplement/article.asp?f=inno-2011-lensx. Physicians also praised the market's response: "From a patient's perspective, I have never seen the potential benefits of a technology so quickly understood and accepted." "Alcon to Acquire LenSx Lasers, Inc., Developer of Femtosecond Laser Technology for Increased Precision of Manual Surgical Steps during Cataract Surgery," BusinessWire (July 06, 2010), <https://www.businesswire.com/news/home/20100706006475/en/Alcon-Acquire-LenSx-Lasers-Developer-Femtosecond-Laser>.

374. Alcon LenSx, Inc., its predecessor, and Alcon Research have continued to layer innovations on top of LenSx®'s original design, including upgraded software and the SoftFit™ Patient Interface, which improves surgical performance and enhances patient comfort. Alcon Research and its predecessors spent millions of dollars per year on software development in the years following launch. That investment paid off in tangible improvements and increased adoption. From launch to at least 2017, Alcon LenSx, Inc., its predecessor, and Alcon Research rolled out yearly product enhancements:

Laser technology that evolves along with your expectations



375. Alcon LenSx, Inc., its predecessor, Alcon Research, and Alcon Vision invested broadly, in addition to technical improvements, to build the market from scratch. For instance, they developed partnerships with doctors and institutions, ran at least fifteen studies demonstrating the continued clinical benefits of the LenSx®, sought additional clinical indications, hired a world-class roster of field service engineers, developed ophthalmology's largest network of clinical application specialists, and heavily invested in physician, staff, and patient education.

376. LenSx® has grown into the number one FLACS system and has been used in over 1.5 million procedures, more than any other FLACS system worldwide. Having literally created the market for FLACS through its innovation, LenSx® has

been the clear and consistent leader in the FLACS market, with approximately 55% of the global market share based on number of procedures performed.

377. After LenSx® was released, numerous companies introduced competing FLACS systems into the marketplace, including the AMO Accused Infringers' CATALYS®, Bausch + Lomb's VICTUS®, Ziemer's Femto LDV Z8, and LENSAR® by LensAR.

378. In order to protect its substantial investments in LenSx®, Alcon LenSx and its predecessor sought and were awarded several patents for this cutting-edge system, covering specific aspects of the LenSx® system that result in demonstrable improvements in the procedure. Five examples of these patented technologies are U.S. Patent Nos. 8,398,236; 9,849,036; 9,622,913; 9,456,925; and 9,427,356 (collectively, "the Alcon Asserted Patents"). These patented technologies represent important developments and innovations in cataract surgery, and are critically important to Alcon Patent Plaintiffs' customers and clients, and the success of Alcon Patent Plaintiffs' businesses.

379. AMO Accused Infringers, by contrast, followed LenSx® onto the U.S. market in 2012 with their CATALYS® Precision Laser System ("CATALYS®") and have been playing catch-up ever since. Rather than investing in their own innovations, CATALYS® has infringed Alcon Patent Plaintiffs' patents by including similar architecture to LenSx®, similarly correcting for lens tilt, and using

similar versatile fragmentation patterns. The AMO Accused Infringers' infringement of Alcon Patent Plaintiffs' patents must be enjoined.

AMO'S INFRINGEMENT

The Infringing Catalys® System

380. CATALYS® was originally developed by OptiMedica and launched in the U.S. in early 2012, a year after the launch of LenSx®. Now, the AMO Accused Infringers manufacture and sell the CATALYS® Precision Laser System, a competitor to LenSx®.

381. CATALYS® combines a femtosecond laser with OCT imaging to perform FLACS procedures. The OCT image is used to correct for lens tilt, generating more precise cuts for better patient outcomes. Lens tilt is a result of the patient's eye docking to the laser system at an angle, resulting in a tilted lens relative to the laser system.

382. During the procedure, the CATALYS® system must account for the tilted lens in order to provide for improved outcomes. The 2018 CATALYS® brochure describes its correction for lens tilt: "Back Your Outcomes with guided delivery that accounts for lens tilt ..." and "[t]he CATALYS® System detects lens tilt and adjusts the safety zone accordingly.... If lens tilt is not detected, the volume of lens fragmentation is not optimized." Without correction for lens tilt, "only part of the lens is fragmented" and the "outer zones will not be fragmented." Thus, the

photodisruption generated by CATALYS®’s laser tracks the natural curvature of the lens to optimize fragmentation. The User Manual states CATALYS® takes “measurements... along a vector orthogonal to the tilt of the lens” and that the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” Thus, the precision of the capsulotomy incision depends on adjustment for lens tilt.

383. CATALYS® includes similar architecture to LenSx® and versatile fragmentation patterns. On information and belief, CATALYS® includes precise architecture that increases efficiency and reduces detrimental scan freezes and jitters due to the data-heavy processing of OCT images. The ability to use an OCT-guided laser to make cuts in the diseased lens in a variety of patterns is a technique known as lens fragmentation. This technique reduces the amount of potentially damaging ultrasonic energy needed for phacoemulsification.

384. CATALYS® is a direct competitor of LenSx® and has always trailed LenSx® in the marketplace. CATALYS® currently has a 30% share of the U.S. FLACS market.

385. OptiMedica was purchased by Abbott Medical Optics, the AMO Accused Infringers’ predecessor, in 2013.

386. Johnson & Johnson purchased Abbott Medical Optics in 2017, and it is now part of the JJSV brand.

387. Upon information and belief, AMO Development makes, uses, offers to sell, and/or sells CATALYS® and consumables in the United States, and supplies or causes to be supplied CATALYS® and consumables from the United States for use abroad. Upon information and belief, AMO Development researches and develops improvements to CATALYS®.

388. Upon information and belief, AMO Manufacturing makes, uses, offers to sell, and/or sells CATALYS® and consumables in the United States, and supplies or causes to be supplied CATALYS® and consumables from the United States for use abroad. Upon information and belief, CATALYS® is manufactured at facilities operated by AMO Manufacturing in the United States and is distributed both domestically and internationally.

389. Upon information and belief, JJSV makes, uses, offers to sell, and/or sells CATALYS® and consumables in the United States, and supplies or causes to be supplied CATALYS® and consumables from the United States for use abroad. According to the FDA's website, JJSV is the owner/operator of AMO Manufacturing, manufacturer of CATALYS®. Upon information and belief, CATALYS® is manufactured at facilities operated by JJSV in the United States and distributed both domestically and internationally.

390. Upon information and belief, AMO Sales and Service makes, uses, offers to sell, and/or sells CATALYS® and consumables in the United States, and supplies or causes to be supplied CATALYS® and consumables from the United States for use abroad. Upon information and belief, AMO Sales and Service acts as a distributor for CATALYS® both domestically and internationally. Upon information and belief, AMO Sales and Service is responsible for repair and maintenance of CATALYS® systems used by their customers.

391. Upon information and belief, AMO Development, AMO Manufacturing, AMO Sales and Service, and JJSV act as agents of each other and/or operate in concert as integrated parts of the same business group with respect to CATALYS®.

AMO Accused Infringers' Knowledge of the Alcon Asserted Patents

392. The AMO Accused Infringers had actual notice of the Alcon Asserted Patents and their infringement by at least as early as May 11, 2020, when Alcon Patent Plaintiffs sent JJSV a letter specifically identifying these patents and stating that the CATALYS® system infringes each of them. A true and correct copy of Alcon Patent Plaintiffs' May 11, 2020 letter is attached to this Complaint as Exhibit 1.

393. On May 22, 2020, Alcon Patent Plaintiffs provided JJSV with representative claim charts from each asserted patent family. JJSV failed to identify any missing limitation of the patent claims in response to that correspondence.

COUNT XXXIII

(Infringement of U.S. Patent No. 8,398,236)

394. Alcon Patent Plaintiffs incorporate by reference the allegations in paragraphs 1 through 393.

395. U.S. Patent No. 8,398,236 (“the ‘236 patent”), entitled “Image-Guided Docking For Ophthalmic Surgical Systems,” was duly and legally issued by the U.S. Patent and Trademark Office (“USPTO”) on March 19, 2013. The named inventors of the ‘236 patent are Adam Juhasz and Kostadin Vardin. A true and correct copy of the ‘236 patent is attached to this Complaint as Exhibit 2.

396. Alcon Inc. and Alcon Research are the owners of the ‘236 patent and have the full right to enforce, license, and seek past damages for the ‘236 patent.

397. Alcon Research was the exclusive licensee of the ‘236 patent.

398. Alcon Vision is the exclusive licensee of the ‘236 patent.

399. The ‘236 patent is valid and enforceable.

400. Alcon Patent Plaintiffs’ ‘236 patent, including at least claim 35, is directed to a method of controlling an ophthalmic imaging. Generally, this patent is directed to the use of OCT in conjunction with ophthalmic surgery and the patient

docking process, increasing the efficiency of the system and reducing lag. Specifically, the patent solves the problem of detrimental scan freezes and jitters due to the slow speed of a general-purpose data buffer in processing OCT images. The patented solution includes use of dedicated electronics components, including a dedicated analog input-output board with dedicated memory controller and data buffer for the OCT imaging system.

401. Claim 35 of the '236 patent recites:

35. A method of controlling an ophthalmic imaging, the method comprising the steps of:

computing scanning control data by a processor for an optical coherence tomographic imaging system;

storing the scanning control data into a dedicated data buffer partially under the control of a memory controller;

transferring the scanning control data from the dedicated data buffer to a signal converter through a dedicated channel; and

sending scanning signals to a scanning controller by an output module, wherein

the scanning signals are converted from the scanning control data by the signal converter.

402. CATALYS® includes a method for controlling an ophthalmic system.

The 2019 User Manual states that “[t]he CATALYS® System uses an Optical Coherence Tomography (OCT) subsystem to create a three-dimensional model of the anterior portion of the eye to guide the laser treatment.” The system includes an

“INTEGRAL GUIDANCE system imaging.” The User Manual discloses “[a]fter verifying that the video image of the patient’s eye is sharp and clear, press the FLUID CONFIRMED button to initiate INTEGRAL GUIDANCE System imaging. A check mark will appear next to the Verify Fluid panel after pressing the FLUID CONFIRMED. The force indicators will also change from only showing a red band to showing yellow, orange, and red bands, indicating different severity levels of forces being exerted by the patient on the disposable lens.” The User Manual discloses “[a]fter capturing and locking the suction ring; verifying that the video image of the eye is sharp and clear; and pressing the FLUID CONFIRMED button on the final Docking Screen, the Surface Mapping Review Screen displays, and INTEGRAL GUIDANCE System imaging begins automatically. The initial Surface Mapping Review Screen displays axial and sagittal cross-section images of the corneal surfaces.” The User Manual further states “[p]ress the FLUID CONFIRMED button on the final Docking Screen to start INTEGRAL GUIDANCE system imaging.” “After INTEGRAL GUIDANCE system imaging is complete, view the INTEGRAL GUIDANCE System data on the Surface Mapping Review Screen, and inspect the surface fits and overlaid incision patterns to ensure accuracy.”

403. Further, CATALYS® is marked with U.S. Patent No. 10,463,539 to OptiMedica (“the ’539 patent”) among others. On information and belief, CATALYS® practices the features disclosed in the ’539 patent.

404. CATALYS® performs a method including computing scanning control data by a processor for an optical coherence tomographic imaging system. As previously discussed, the 2019 User Manual states that “[t]he CATALYS® System uses an Optical Coherence Tomography (OCT) subsystem to create a three-dimensional model of the anterior portion of the eye to guide the laser treatment.” The system includes “INTEGRAL GUIDANCE system imaging.” The ’539 patent states “[t]he ranging subsystem 46 is configured to measure the spatial disposition of eye structures in three dimensions.... In many embodiments, the ranging subsystem 46 utilizes optical coherence tomography (OCT) imaging.” “In the embodiment of FIG. 3, the ranging subsystem 46 includes an OCT imaging device.” The ’539 patent further states “[a]n OCT scan of the eye can be used to measure the spatial disposition (*e.g.*, three dimensional coordinates such as X, Y, and Z of points on boundaries) of structures of interest in the patient’s eye 43.” “The shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” The ’539 patent

shows the relationship between the control electronics, including the processor, to the ranging subsystem in Fig. 2. The '539 patent further describes “[t]he control electronics 54 controls the operation of and can receive input from the cutting laser subsystem 44, the ranging subsystem 46....” “The control electronics 54 can include any suitable components, such as one or more processor... and one or more memory storage devices.” The '539 patent states that “such processors include dedicated circuitry” and “[o]ne or more of the steps of the method 400 may be performed with the circuitry as described herein, for example one or more of the processor or logic circuitry....”

405. CATALYS® performs a method including storing the scanning control data into a dedicated data buffer partially under the control of a memory controller. The 2019 User Manual states “[t]he CATALYS® System consists of three integrated optical subsystems, each controlled and monitored by dedicated electronics.” It also states “[t]he system is controlled by a dedicated field programmable gate array (FPGA) and is accessed via the host computer.” The '539 patent shows the relationship between the control electronics, including the processor, to the ranging subsystem in Fig. 2 and includes a processor, memory, and dedicated circuitry. “The control electronics 54 can include any suitable components, such as one or more processor... and one or more memory storage devices.” A memory “is coupled to the processor 55 in order to store data used by the processor...” and “[t]he memory

57 can be local or distributed as appropriate to the particular application. Memory 57 may include a number of memories....”

406. CATALYS® performs a method including transferring the scanning control data from the dedicated data buffer to a signal converter through a dedicated channel. The 2019 User Manual states “[t]he CATALYS® System consists of three integrated optical subsystems, each controlled and monitored by dedicated electronics.” It also states “[t]he system is controlled by a dedicated field programmable gate array (FPGA) and is accessed via the host computer.” The ’539 patent discloses “[t]he control electronics 54 controls the operation of and can receive input from the cutting laser subsystem 44, the ranging subsystem 46....” “The control electronics 54 can include any suitable components, such as one or more processor ... and one or more memory storage devices.” The ’539 patent further discloses “[t]he control electronics 54 may comprise a processor controller 55 (referred to herein as a processor) that is used to perform calculations related to system operation and provide control signals to the various system elements.” The ’539 patent states that “such processors include dedicated circuitry” and “[t]he memory 57 can be local or distributed as appropriate to the particular application. Memory 57 may include a number of memories....” Fig. 2 of the ’539 patent discloses the communication paths between the control electronics and the shared optics. “The control electronics 54 controls ... the ranging subsystem 46 ... via the

communication paths 60. The communication paths 60 can be implemented in any suitable configuration, including any suitable shared or dedicated communication paths between the control electronics 54 and the respective system components.”

407. CATALYS® performs a method including sending scanning signals to a scanning controller by an output module. The '539 patent discloses “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” Fig. 2 of the '539 patent discloses the relationship between the control electronics, including the memory, and the shared optics, and Fig. 3 details the subsystem including the OCT imaging device and the “Z-tscope.” “An OCT scan of the eye can be used to measure the spatial disposition (e.g., three dimensional coordinates such as X, Y, and Z of points on boundaries) of structures of interest in the patient's eye 43.” The '539 patent states “[t]he OCT source beam … is transmitted through the shared optics 50” and “the OCT sample beam 102 passes through the Z-telescope 84, is redirected by the X-scan device 86 and by the Y-scan device 88....” The '539 patent discloses “the shared optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used

to vary the depth of the focal point within the eye 43.” Further, “[t]he Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The ’539 patent discloses “[t]he X-scan device 86 is controlled by the control electronics” and “[t]he Y-scan device 88 is controlled by the control electronics 54.” “The generated OCT signals that are in turn interpreted by the control electronics to determine the spatial disposition of the structures of interest in the patient’s eye 43.”

408. CATALYS® performs a method in which the scanning signals are converted from the scanning control data by the signal converter. The ’539 patent discloses “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” Fig. 2 of the ’539 patent discloses the relationship between the control electronics, including the memory, and the shared optics and Fig. 3 shows the OCT imaging device and Z-tscole. “An OCT scan of the eye can be used to measure the spatial disposition (e.g., three dimensional coordinates such as X, Y, and Z of points on boundaries) of structures of interest in the patient’s eye 43.” Further, “[t]he ranging subsystem 46 in FIG. 3 includes an OCT light source and detection device 98. The OCT light source and detection device 98 includes a light source that generates and emits an OCT source beam with a suitable broad spectrum.” The ’539

patent states “[t]he OCT source beam … is transmitted through the shared optics 50” and “the OCT sample beam 102 passes through the Z-telescope 84, is redirected by the X-scan device 86 and by the Y-scan device 88....” The ’539 patent discloses “the shared optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Further, “[t]he Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The ’539 patent discloses “[t]he X-scan device 86 is controlled by the control electronics” and “[t]he Y-scan device 88 is controlled by the control electronics 54.” “The generated OCT signals that are in turn interpreted by the control electronics to determine the spatial disposition of the structures of interest in the patient’s eye 43.”

409. Thus, use of the CATALYS® system meets each and every limitation of at least claim 35 of the ’236 patent, either literally and/or under the doctrine of equivalents.

410. AMO Accused Infringers’ testing and use of the CATALYS® in the United States infringe the ’236 patent under 35 U.S.C. § 271(a).

411. AMO Accused Infringers’ customers in the United States also directly infringe the ’236 patent by using CATALYS®. AMO Accused Infringers actively induce infringement of the ’236 patent by encouraging their customers to use

CATALYS®, with knowledge that the induced acts constitute patent infringement and/or with willful blindness to infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, AMO Accused Infringers' inducing acts include marketing CATALYS®, supporting the ongoing use of CATALYS® by providing consumables for use with CATALYS®, and providing installation, maintenance, service, and/or repair of CATALYS®. Additionally, upon information and belief, AMO Accused Infringers publish and provide product documentation and educational materials that instruct and encourage their customers to use CATALYS® in an infringing manner. For example, upon information and belief, AMO Accused Infringers warn customers in the 2019 User Manual for CATALYS® that “[t]o protect operating personnel and patients, this manual should be read thoroughly and understood before operation.” AMO Accused Infringers have known of the '236 patent and of their infringement prior to this litigation, at least since May 2020 pursuant to Alcon Patent Plaintiffs' notice letter identifying the '236 patent and AMO Accused Infringers' infringement thereof. AMO Accused Infringers nevertheless have continued inducing infringement.

412. AMO Accused Infringers also contribute to infringement of the patent by offering to sell and selling CATALYS®, in violation of 35 U.S.C. § 271(c). The CATALYS® system is an apparatus for use in practicing the patented process. AMO Accused Infringers supply customers with the CATALYS® system knowing

it is especially made and especially adapted for a use that infringes the patent. The customer necessarily infringes the patent when it uses CATALYS® for the indicated use in patients undergoing cataract surgery. See JJSV website, <https://www.jnjvisionpro.com/products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”). AMO Accused Infringers specifically list “intended uses in cataract surgery” and do not market CATALYS® for LASIK surgery. *Id.* CATALYS® is not a staple article or commodity of commerce, and it does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use CATALYS® for the indicated uses in a way to avoid infringement of the patent.

413. AMO Accused Infringers are not licensed under the '236 patent.

414. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through the marking of LenSx®.

415. Thus, AMO Accused Infringers’ manufacture, use, offer to sell, sale, and export of CATALYS® in or from the United States infringe at least claim 35 of the '236 patent under 35 U.S.C. § 271(a)-(c).

416. Alcon Patent Plaintiffs have suffered and will suffer damage as a direct and proximate result of AMO Accused Infringers’ infringement of the '236 patent.

Thus, Alcon Patent Plaintiffs are entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

417. Alcon Patent Plaintiffs have been damaged and will continue to be damaged by AMO Accused Infringers' infringement of the '236 patent.

418. Alcon Patent Plaintiffs have suffered and will suffer irreparable harm unless and until AMO Accused Infringers' infringing activities are enjoined by this Court. Alcon Patent Plaintiffs do not have an adequate remedy at law.

COUNT XXXIV

(Infringement of U.S. Patent No. 9,849,036)

419. Alcon Patent Plaintiffs incorporate by reference the allegations in paragraphs 1 through 418.

420. U.S. Patent No. 9,849,036 ("the '036 patent"), entitled "Imaging-Controlled Laser Surgical System," was duly and legally issued by the USPTO on December 26, 2017. The named inventors on the '036 patent are Gautam Chaudhary, Peter Goldstein, Imre Hegedus, Carlos German Suarez, David Calligori, and Michael Karavitis. A true and correct copy of the '036 patent is attached to this Complaint as Exhibit 3.

421. Alcon Inc. and Alcon Research are the owners of the '036 patent and have the full right to enforce, license, and seek past damages for the '036 patent.

422. Alcon Research was the exclusive licensee of the '036 patent.

423. Alcon Vision is the exclusive licensee of the '036 patent.

424. The '036 patent is valid and enforceable.

425. Alcon Patent Plaintiffs' '036 patent is directed to use of OCT image processing to create capsulotomy incisions with an adjustable laser-power parameter, increasing the accuracy of the capsulotomy and improving patient outcomes. For example, prior art capsulotomy incisions were made at a constant depth even when the anterior lens surface was uneven due to lens tilt. The patented solution includes imaging the eye and creating a scan pattern for the capsulotomy incision that tracks an imaged layer of the eye. At least claim 7 is directed to a method of adjusting for lens tilt.

426. Claim 7 of the '036 patent recites:

7. A method, comprising:

generating an image, with an imaging system, of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye;

determining, with an imaging-based laser-controller, z-depths of a sequence of points in a scan-pattern that correspond to the image of the layer;

generating, with the imaging-based laser-controller, a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer;

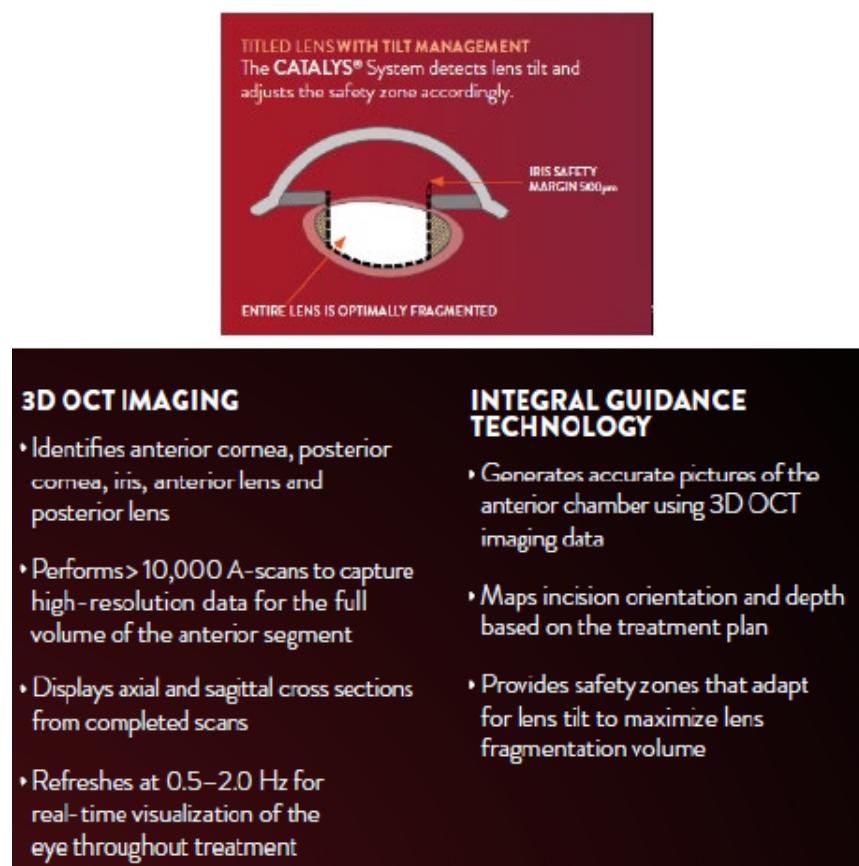
directing, with the imaging-based laser-controller, a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band.

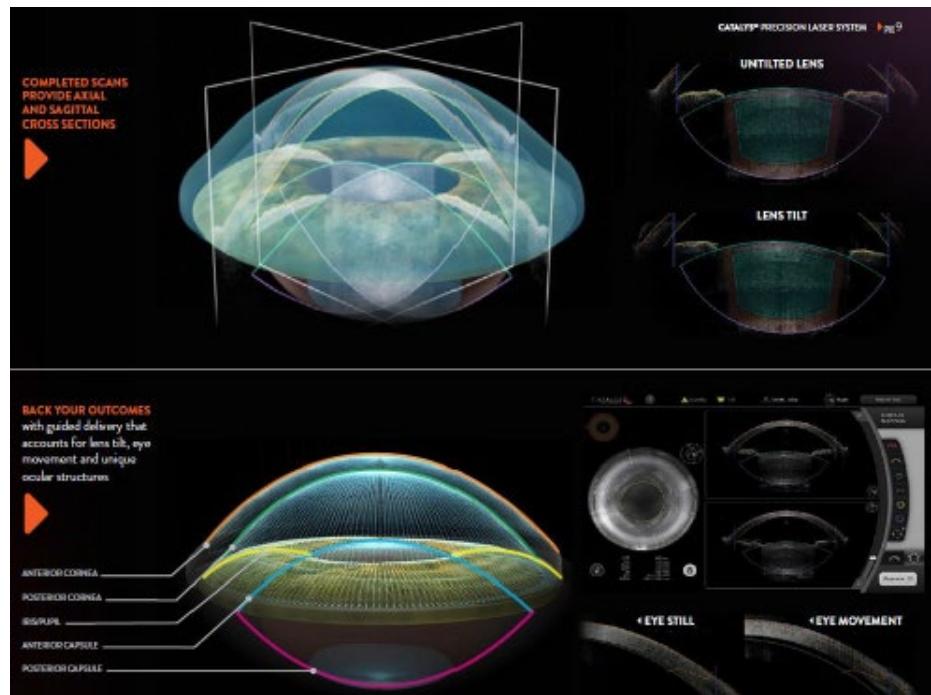
427. CATALYS® is marked with U.S. Patent No. 10,463,539 to OptiMedica (“the ’539 patent”) among others. On information and belief, CATALYS® practices the features disclosed in the ’539 patent.

428. CATALYS® performs a method including generating an image, with an imaging system, of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye. The ’539 patent discloses that “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” The ’539 patent discloses that “the aiming pattern … can optionally be used to designate the boundaries of the treatment pattern,” and “the scan pattern of the laser pulse beam 66 forms on the eye 43 may be further controlled by use of an input device....” “Additionally, the ranging subsystem such as an OCT can be used to detect features or aspects involved with the patient interface. Features can include fiducials placed on the docking structures and optical structures of the disposable lens such as the location of the anterior and posterior surfaces.” The 2019 User Manual discloses that “[t]he CATALYS® System uses an Optical Coherence Tomography (OCT) subsystem to create a three-

dimensional model of the anterior portion of the eye to guide the laser treatment. The OCT system employs an 820–930 nm spectral domain OCT to create three-dimensional images of anterior ocular structures.” Further, the INTEGRAL GUIDANCE System “provid[es] targeted centration for the capsulotomy.” The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” The User Manual states “Pattern-Circular is the only pattern option” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” See also <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo. The User Manual further describes “[i]mportantly, the system-integrated INTEGRAL GUIDANCE System processing ensures that adequate safety margins with respect to iris, lens capsule, and cornea are maintained regardless of eye morphology, orientation, or tilt, thus assuring safe delivery of the treatment laser pulses.” CATALYS® takes “measurements… along a vector orthogonal to the tilt of the lens.” The ’539 patent

states “[t]he ranging subsystem 46 is configured to measure the spatial disposition of eye structures in three dimensions” and “information may then be loaded into the laser 3-D scanning system or used to generate a three dimensional model/representative/image of the cornea, anterior chamber, and lens of the eye, and used to define the cutting patterns used in the surgical procedure.” The 2018 CATALYS® brochure describes accounting for the lens tilt:





429. Publications further describe CATALYS® accounting for lens tilt during the procedure. In *A Catalys for Change in Cataract Surgery*, Robert Rivera, MD, and a CATALYS® user is quoted saying “[y]ou get an axial and sagittal view of the structures so, in the case of lens tilt, the laser automatically adjusts for the tilt and tilts the anterior capsulotomy treatment. It also automatically creates a 500- μm safe zone to keep the treatment away from the posterior capsule.” Bethke, W., “A Catalys for Change in Cataract Surgery,” Review of Ophthalmology (Oct. 4, 2012), <https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>. Further, *Get to Know Your Femtosecond Options* states “[CATALYS®] does a great job figuring out the tilt and position of the lens,’ Dr. Koch avers. It will adjust the photodisruption pattern based on any tilt, helping to avoid complications from disrupting the wrong structures.” Bethe, W. “Get to Know Your Femtosecond

Options,” Review of Ophthalmology (July 6, 2015),
<https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>.

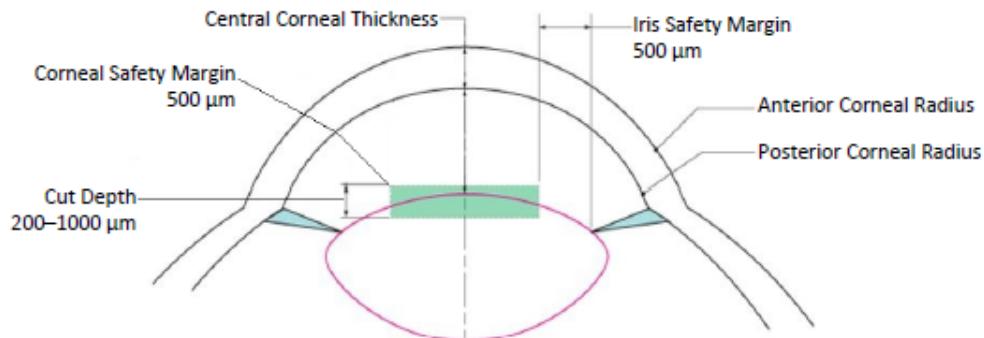
430. CATALYS® performs a method including determining, with an imaging-based laser-controller, z-depths of a sequence of points in a scan-pattern that correspond to the image of the layer. The '539 patent states “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” Scan patterns of the laser beam can be used to designate boundaries of the treatment pattern, and the OCT subsystem creates images of the ocular structures to provide targeted centration for the capsulotomy. *See* '539 patent; User Manual; 2018 CATALYS® brochure. Further, the incisions are guided by the OCT data and adjust for lens tilt. *See* '539 patent; User Manual; 2018 CATALYS® brochure; Bethke, W., “A Catalys for Change in Cataract Surgery,” Review of Ophthalmology (Oct. 4, 2012),
<https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>; Bethe, W. “Get to Know Your Femtosecond Options,” Review of Ophthalmology (July 6, 2015), <https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>.

431. CATALYS® performs a method including generating, with the imaging-based laser-controller, a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer. CATALYS® uses a circular pattern that adjusts for lens tilt. *See* '539 patent; User Manual; 2018 CATALYS® brochure; Bethke, W., "A Catalys for Change in Cataract Surgery," Review of Ophthalmology (Oct. 4, 2012), <https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>; Bethe, W. "Get to Know Your Femtosecond Options," Review of Ophthalmology (July 6, 2015), <https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>. The 2019 User Manual further discloses the posterior cornea safety margin:

Figure 3.59 Capsulotomy Details Screen



Figure 4.2 Corneal and Iris Safety Margins

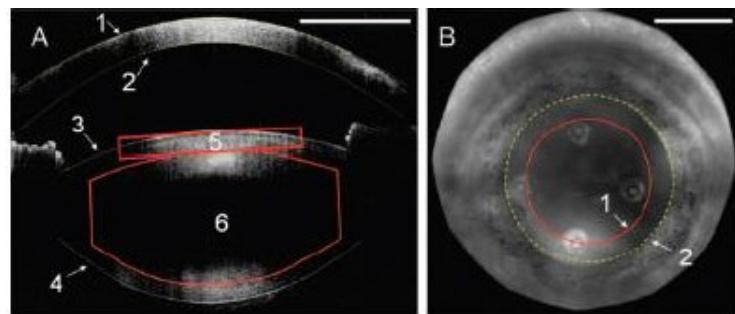


Cross-sectional view highlighting geometric relationships of lens (shown in red) and respective safety margins for iris and cornea.

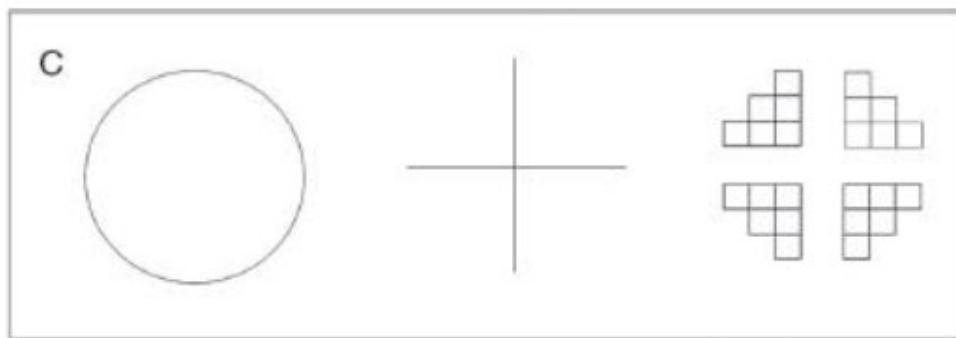
432. Similarly, publications disclose that the CATALYS® system identifies the anterior and posterior surface of the lens. See Palanker DV, et al., Femtosecond laser-assisted cataract surgery with integrated optical coherence tomography, SciTransl Med 2010, available at <https://pubmed.ncbi.nlm.nih.gov/21084720/> (hereinafter “Palanker”) (“The three-dimensional map of the lens and the anterior chamber is acquired with FDOCT, and the software automatically identifies the

anterior and posterior surfaces of the lens and cornea, as well as the iris (Fig. 3A”).

Figure 3A in Palanker, further discloses an “OCT image of the eye with outlined boundaries of the cornea (1 and 2) and lens capsule (3 and 4). The capsulotomy pattern (5) and lens segmentation pattern (6) are shown in solid red.” Figure 3B is a “[v]iew of the eye in the near-infrared video camera, with overlaid guidance lines indicating a planned capsulotomy pattern (1) and a boundary of the pupil (2).”



433. Figure 3C is a “[t]op view of the circular capsulotomy pattern, a cross-pattern for lens segmentation, and the nucleus fragmentation pattern.”



434. Figure 3D is a “[t]hree-dimensional representation of the capsulotomy and cross-segmentation patterns in the lens alone (left) and inside the eye (right).”



435. CATALYS® performs a method including directing, with the imaging-based laser-controller, a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band. The '539 patent discloses “the shared optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Further, the '539 patent discloses that “[u]sing the assembly 62, optical beam can scanned in the patient’s eye” and the laser “can be focused into eye tissue … to cause photodisruption around the focal point.” Figure 3 discloses the components of the shared optics, including the Z-Tscope. The '539 patent discloses “[f]ollowing the beam combiner 82, the laser pulse beam 66 continues through a Z-telescope 84, which is operable to scan focus position of the laser pulse beam 66 in the patient’s eye 43 along the Z axis.... In this way, the focus position of the spot in the patient’s eye 43 moves along the Z axis.” Further, “[t]he motion can be nonlinear and directed via a model or a

calibration from measurement or a combination of both.” “The Z-telescope 84 functions as z-scan device for scanning the focus point of the laser-pulse beam 66 in the patient’s eye 43. The Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The ’539 patent discloses that the “X-scan device” and “Y-scan device” are “controlled by the control electronics 54” and “[m]odeling or calibrated measurement of the relationship or combination of both can be determined and used to direct the location of the beam.” The User Manual states “Pattern-Circular is the only pattern option” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces,

to center the capsulotomy.” See also

<https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo.

436. Thus, the use of the CATALYS® system meets each and every limitation of at least claim 7 of the ’036 patent, either literally and/or under the doctrine of equivalents.

437. AMO Accused Infringers’ testing and use of CATALYS® in the United States infringe the ’036 patent under 35 U.S.C. § 271(a).

438. AMO Accused Infringers’ customers in the United States also directly infringe the ’036 patent by using CATALYS®. AMO Accused Infringers actively

induce infringement of the '036 patent by encouraging their customers to use CATALYS®, with knowledge that the induced acts constitute patent infringement and/or with willful blindness to infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, AMO Accused Infringers inducing acts include marketing CATALYS®, supporting the ongoing use of CATALYS® by providing consumables for use with CATALYS®, and providing installation, maintenance, service, and/or repair of CATALYS®. Additionally, upon information and belief, AMO Accused Infringers publish and provide product documentation and educational materials that instruct and encourage their customers to use CATALYS® in an infringing manner. For example, upon information and belief, AMO Accused Infringers warn customers in the 2019 User Manual for CATALYS® that “[t]o protect operating personnel and patients, this manual should be read thoroughly and understood before operation.”

439. AMO Accused Infringers have known of the '036 patent and of their infringement prior to this litigation, at least since May 2020 pursuant to Alcon Patent Plaintiffs' notice letter identifying the '036 patent and AMO Accused Infringers' infringement thereof. AMO Accused Infringers nevertheless have continued inducing infringement.

440. AMO Accused Infringers also contribute to infringement of the patent by offering to sell and selling CATALYS®, in violation of 35 U.S.C. § 271(c). The

CATALYS® system is an apparatus for use in practicing the patented process. AMO Accused Infringers supply customers with the CATALYS® system knowing it is especially made and especially adapted for a use that infringes the patent. The customer necessarily infringes the patent when it uses CATALYS® for the indicated use in patients undergoing cataract surgery. See JJSV website, <https://www.jnjvisionpro.com/products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”). AMO Accused Infringers specifically list “intended uses in cataract surgery” and do not market CATALYS® for LASIK surgery. *Id.* CATALYS® is not a staple article or commodity of commerce, and it does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use CATALYS® for the indicated uses in a way to avoid infringement of the patent.

441. AMO Accused Infringers are not licensed under the ’036 patent.

442. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through the marking of LenSx®.

443. Thus, AMO Accused Infringers’ manufacture, use, offer to sell, sale, and export of CATALYS® in or from the United States infringe at least claim 7 of the ’036 patent under 35 U.S.C. § 271(a)-(c).

444. Alcon Patent Plaintiffs will suffer damage as a direct and proximate result of AMO Accused Infringers' infringement of the '036 patent. Thus, Alcon Patent Plaintiffs are entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

445. Alcon Patent Plaintiffs have been damaged and will continue to be damaged by AMO Accused Infringers' infringement of the '036 patent.

446. Alcon Patent Plaintiffs have suffered and will suffer irreparable harm unless and until AMO Accused Infringers' infringing activities are enjoined by this Court. Alcon Patent Plaintiffs do not have an adequate remedy at law.

COUNT XXXV

(Infringement of U.S. Patent No. 9,622,913)

447. Alcon Patent Plaintiffs incorporate by reference the allegations in paragraphs 1 through 446.

448. U.S. Patent No. 9,622,913 ("the '913 patent"), entitled "Imaging-Controlled Laser Surgical System," was duly and legally issued by the USPTO on April 18, 2017. The named inventors on the '913 patent are Gautam Chaudhary, Peter Goldstein, Imre Hegedus, Carlos German Suarez, David Calligori, and Michael Karavitis. A true and correct copy of the '913 patent is attached to this Complaint as Exhibit 4.

449. Alcon Inc. and Research are the owners of the '913 patent and have the full right to enforce, license, and seek past damages for the '913 patent.

450. Alcon Research was the exclusive licensee of the '913 patent.

451. Alcon Vision is the exclusive licensee of the '913 patent.

452. The '913 patent is valid and enforceable.

453. Alcon Patent Plaintiffs' '913 patent is directed to systems configured to generate capsulotomy incisions with an adjustable laser-power parameter. Similar to the '036 patent, this patent is directed to use of OCT image processing to image a layer of the eye and to create a scan pattern based on the image. At least claim 1 is directed to a system configured to adjust for lens tilt.

454. Claim 1 of the '913 patent recites:

1. An imaging-based laser system, comprising:

a laser-beam system, including

a laser engine, configured to generate a beam of laser pulses,

a beam attenuator, configured to modify a laser-power parameter of the laser pulses, wherein the laser-power parameter is one of a pulse energy, a pulse power, a pulse length and a pulse repetition rate,

and a beam scanner, configured to scan the beam to points of a cylindrical scan-pattern in an eye; and

an imaging-based laser-controller, configured to:

image a layer in the eye that is tilted relative to an optical axis of the laser system,

determine z-depths of a sequence of points in the cylindrical scan-pattern that correspond to the imaged layer in the eye,

generate a tracking band within the cylindrical scan pattern defining a cut to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer,

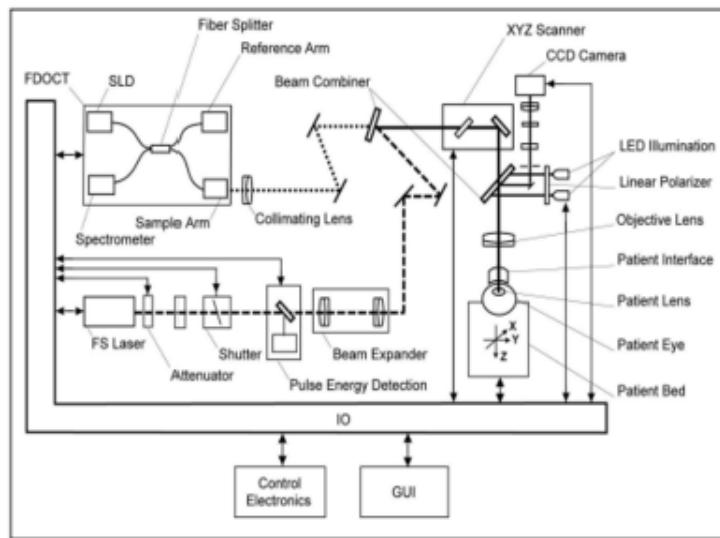
cause the beam scanner to scan the beam of laser pulses to the points of the cylindrical scan-pattern, and

cause the beam attenuator to control the laser-power parameter of the laser pulses such that a laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold.

455. CATALYS® is marked with U.S. Patent No. 10,463,539 to OptiMedica (“the ’539 patent”) among others. On information and belief, CATALYS® practices the features disclosed in the ’539 patent.

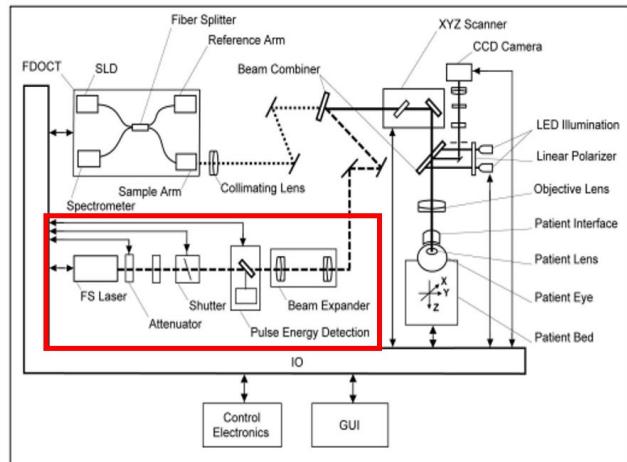
456. CATALYS® is an imaging-based laser system. The 2019 User Manual discloses that “[t]he OPTIMEDICA CATALYS® Precision Laser System is an integrated scanning laser system that is used by cataract surgeons to create a precise anterior capsulotomy and/or subsequent fragmentation (phacofragmentation) of the crystalline lens, with or without single plane and multi-plane arc cuts/incisions in the cornea. Treatment is accomplished through the use of ultrafast ($\tau \sim 10\text{-}13\text{s}$, or hundreds of femtoseconds [FS]) infrared laser pulses.” The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying

FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” OCT data guides the incisions and the optical subsystems include dedicated electronics. *See User Manual; '539 patent.* Figures 2 and 3 in the '539 patent disclose the relationship between the cutting laser subsystem, shared optics, ranging subsystem, communication paths, and control electronics. Figure S2 in Palanker discloses a “simplified diagram of the system, including the imaging (OCT) and the treatment (femtosecond laser) modules.”



457. CATALYS® includes a laser-beam system. Figure 3 of the '539 patent discloses the “cutting laser 44.” Further Palanker Figure S2 also discloses “the treatment (femtosecond laser) modules:

Fig. S2.
Simplified diagram of
the system, including
the imaging (OCT) and
the treatment
(femtosecond laser)
modules.



(annotations added).

458. CATALYS® includes a laser engine, configured to generate a beam of laser pulses. CATALYS® is a laser system that includes a laser engine that generates laser pulses. *See '539 patent; Palanker Fig. S2.* The '539 patent states “the cutting laser subsystem 44 incorporates femtosecond (FS) laser technology.... [S]ystem 2 can be configured to use a cutting laser subsystem 44 that produces laser pulses....” The '539 patent discloses “[t]he cutting laser subsystem 44 includes an ultrafast (UF) laser 64 (e.g., a femtosecond laser).... For example, short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” The 2019 User Manual discloses that “[t]he CATALYS® System is classified as a CDRH Class 4 stand-alone laser device, because of intentional laser exposure to the patient's eye. The treatment laser is a diode-pumped solid-state configuration with a 1030 (± 5) nm

center wavelength incorporating femtosecond (FS) laser technology.” “Treatment is accomplished through the use of ultrafast ($\tau \sim 10\text{-}13\text{s}$, or hundreds of femtoseconds [FS]) infrared laser pulses.” The User Manual also discloses the system specifications:

Treatment Laser	
Type	Diode pumped solid-state, mode-locked
Center wavelength	1030 nm (± 5 nm)
Pulse energy	1 - 10 μJ
Pulse duration	< 600 fs
Pulse rep. rate	120 kHz $\pm 5\%$, with integer down sampling when modulated
CDRH laser class (21 CFR 1040)	Class 4

The '539 patent further discloses that the “cutting laser subsystem 44 is controlled by the control electronics 54 and the user, via the control panel/GUI 56 and the user interface devices 58, to create a laser pulse beam 66.”

459. CATALYS® includes a beam attenuator, configured to modify a laser-power parameter of the laser pulses, wherein the laser-power parameter is one of a pulse energy, a pulse power, a pulse length and a pulse repetition rate. Figure 3 of the '539 patent discloses the attenuator and the specification states “[t]he cutting laser subsystem 44 can include control and conditioning components” including “a beam attenuator to control the energy of the laser pulse and the average power of the pulse-train.” “The attenuator 70 is used to adjust the transmission of the laser beam and thereby the energy level of the pulses in the laser pulse beam 66.”

460. CATALYS® includes a beam scanner, configured to scan the beam to points of a cylindrical scan-pattern in an eye. The '539 patent discloses “the shared

optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Further, the ’539 patent discloses “short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” The ’539 patent discloses “[f]ollowing the beam combiner 82, the laser pulse beam 66 continues through a Z-telescope 84, which is operable to scan focus position of the laser pulse beam 66 in the patient’s eye 43 along the Z axis.... In this way, the focus position of the spot in the patient’s eye 43 moves along the Z axis.” Further, “[t]he motion can be nonlinear and directed via a model or a calibration from measurement or a combination of both.” “The Z-telescope 84 functions as z-scan device for scanning the focus point of the laser-pulse beam 66 in the patient’s eye 43. The Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The ’539 patent discloses that the “X-scan device” and “Y-scan device” are “controlled by the control electronics 54” and “[m]odeling or calibrated measurement of the relationship or combination of both can be determined and used to direct the location of the beam.” The User Manual states “Pattern-Circular is the only pattern option” and the “Scanned Capsule—uses

the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” See also <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo. The 2019 User Manual further discloses for the incision depth the “axial extent of capsulotomy cylinder pattern, centered around the detected lens anterior surface.”

461. CATALYS® includes an imaging-based laser-controller. Palanker Fig. S2 and Figure 3 and the specification of the '539 patent disclose the ranging subsystem that includes an OCT imaging device. Palanker Figure S2 discloses the OCT system. Figure 3 of the '539 patent shows the OCT imaging device and Z-tscope. “An OCT scan of the eye can be used to measure the spatial disposition (e.g., three dimensional coordinates such as X, Y, and Z of points on boundaries) of structures of interest in the patient’s eye 43.” Further, “[t]he ranging subsystem 46 in FIG. 3 includes an OCT light source and detection device 98,” and the “ranging subsystem 46 is configured to measure the spatial disposition of eye structures in three dimensions.” The '539 patent shows the relationship between the control electronics, including the processor, to the ranging subsystem in Fig. 2 and includes a processor, memory, and dedicated circuitry. “The control electronics 54 can include any suitable components, such as one or more processor... and one or more

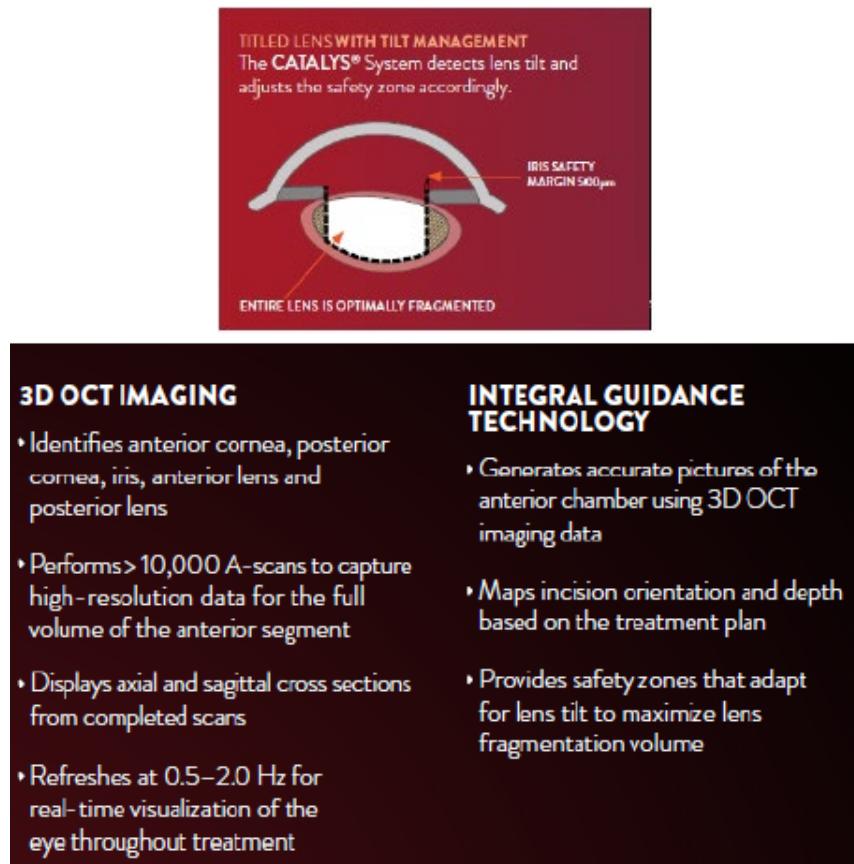
memory storage devices.” The 2019 User Manual also states “[t]he system is controlled by a dedicated field programmable gate array (FPGA) and is accessed via the host computer.”

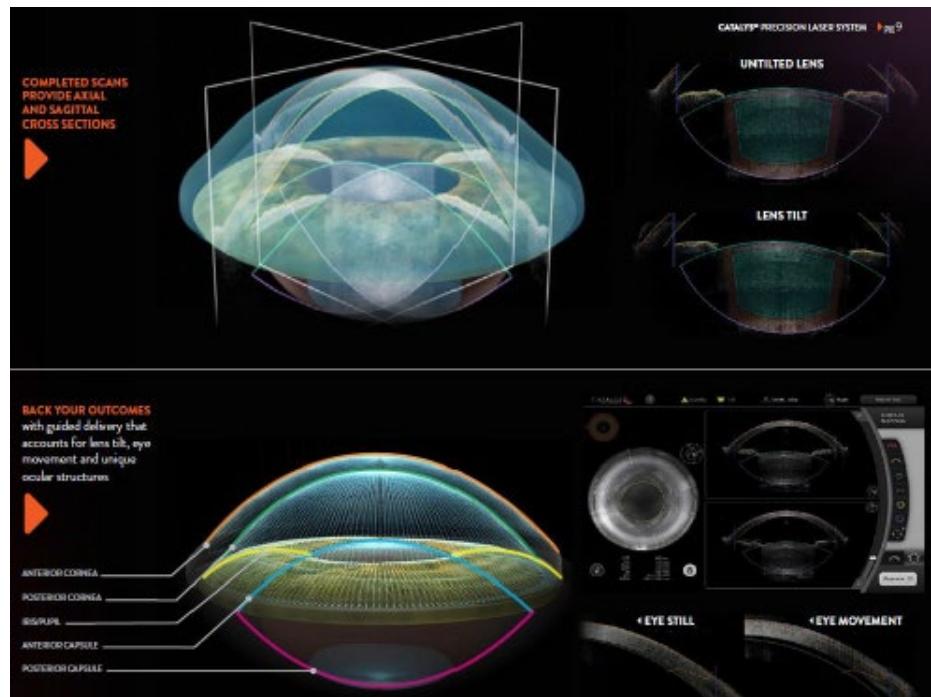
462. CATALYS® includes an imaging-based laser-controller, configured to image a layer in the eye that is tilted relative to an optical axis of the laser system. The ’539 patent discloses that “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” The ’539 patent discloses that “the aiming pattern ... can optionally be used to designate the boundaries of the treatment pattern,” and “the scan pattern of the laser pulse beam 66 forms on the eye 43 may be further controlled by use of an input device....” “Additionally, the ranging subsystem such as an OCT can be used to detect features or aspects involved with the patient interface. Features can include fiducials placed on the docking structures and optical structures of the disposable lens such as the location of the anterior and posterior surfaces.” The 2019 User Manual discloses that [t]he CATALYS® System uses an Optical Coherence Tomography (OCT) subsystem to create a three-dimensional model of the anterior portion of the eye to guide the laser treatment. The OCT system employs an 820–930 nm spectral domain OCT to create three-dimensional images of anterior ocular

structures.” Further, the INTEGRAL GUIDANCE System “provid[es] targeted centration for the capsulotomy.” The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” The User Manual states “Pattern-Circular is the only pattern option” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” *See also* <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo. The User Manual further describes “[i]mportantly, the system-integrated INTEGRAL GUIDANCE System processing ensures that adequate safety margins with respect to iris, lens capsule, and cornea are maintained regardless of eye morphology, orientation, or tilt, thus assuring safe delivery of the treatment laser pulses.” CATALYS® takes “measurements… along a vector orthogonal to the tilt of the lens.” The ’539 patent states “[t]he ranging subsystem 46 is configured to measure the spatial disposition of eye structures in three dimensions” and “information may then be loaded into the laser 3-D scanning system or used to generate a three

dimensional model/representative/image of the cornea, anterior chamber, and lens of the eye, and used to define the cutting patterns used in the surgical procedure.”

The 2018 CATALYS® brochure describes accounting for the lens tilt:





463. Publications further describe CATALYS® accounting for lens tilt during the procedure. In *A Catalys for Change in Cataract Surgery*, Robert Rivera, MD, and a CATALYS® user is quoted saying “[y]ou get an axial and sagittal view of the structures so, in the case of lens tilt, the laser automatically adjusts for the tilt and tilts the anterior capsulotomy treatment. It also automatically creates a 500- μm safe zone to keep the treatment away from the posterior capsule.” Bethke, W., “A Catalys for Change in Cataract Surgery,” Review of Ophthalmology (Oct. 4, 2012), <https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>. Further, *Get to Know Your Femtosecond Options* states “[CATALYS®] does a great job figuring out the tilt and position of the lens,’ Dr. Koch avers. It will adjust the photodisruption pattern based on any tilt, helping to avoid complications from disrupting the wrong structures.” Bethe, W. “Get to Know Your Femtosecond

Options,” Review of Ophthalmology (July 6, 2015),

<https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>.

464. CATALYS® includes an imaging-based laser-controller, configured to determine z-depths of a sequence of points in the cylindrical scan-pattern that correspond to the imaged layer in the eye. The User Manual states “Pattern-Circular is the only pattern option,” incision depth is the “axial extent of capsulotomy cylinder pattern, centered around the detected lens anterior surface,” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” *See also* <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo. The ’539 patent states “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” Scan patterns of the laser beam can be used to designate boundaries of the treatment pattern, and the OCT subsystem creates images of the ocular structures to provide targeted centration for the capsulotomy. *See* ‘539 patent; User Manual;

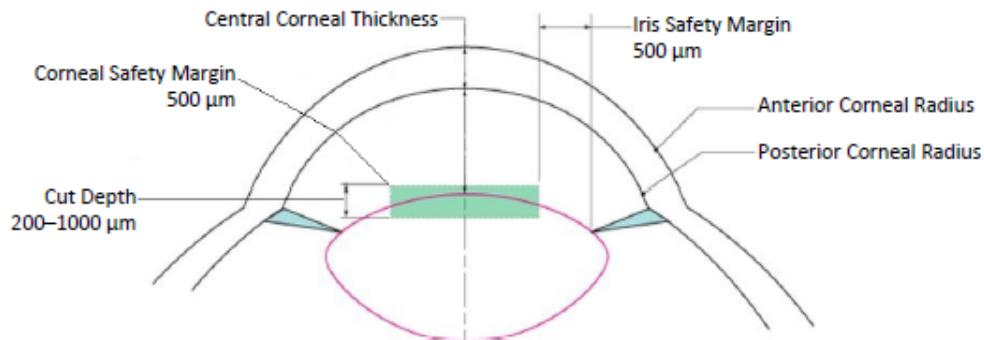
2018 CATALYS® brochure. Further, the incisions are guided by the OCT data and adjust for lens tilt. *See* '539 patent; User Manual; 2018 CATALYS® brochure; Bethke, W., “A Catalys for Change in Cataract Surgery,” Review of Ophthalmology (Oct. 4, 2012), <https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>; Bethe, W. “Get to Know Your Femtosecond Options,” Review of Ophthalmology (July 6, 2015), <https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>.

465. CATALYS® includes an imaging-based laser-controller, configured to generate a tracking band within the cylindrical scan pattern defining a cut to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer. CATALYS® uses a circular pattern that adjusts for lens tilt. *See* '539 patent; User Manual; 2018 CATALYS® brochure; Bethke, W., “A Catalys for Change in Cataract Surgery,” Review of Ophthalmology (Oct. 4, 2012), <https://www.reviewofophthalmology.com/article/a-catalys-for-change-in-cataract-surgery>; Bethe, W. “Get to Know Your Femtosecond Options,” Review of Ophthalmology (July 6, 2015), <https://www.reviewofophthalmology.com/article/get-to-know-your--femtosecond-options>. The 2019 User Manual further discloses the posterior cornea safety margin:

Figure 3.59 Capsulotomy Details Screen



Figure 4.2 Corneal and Iris Safety Margins



Cross-sectional view highlighting geometric relationships of lens (shown in red) and respective safety margins for iris and cornea.

Similarly, publications disclose that the CATALYS® system identifies the anterior and posterior surface of the lens. See Palanker DV, et al., Femtosecond laser-assisted cataract surgery with integrated optical coherence tomography, SciTransl Med 2010, available at <https://pubmed.ncbi.nlm.nih.gov/21084720/> (hereinafter “Palanker”) (“The three-dimensional map of the lens and the anterior chamber is acquired with FDOCT, and the software automatically identifies the anterior and posterior surfaces

of the lens and cornea, as well as the iris (Fig. 3A)”). Figure 3A in Palanker, further discloses an “OCT image of the eye with outlined boundaries of the cornea (1 and 2) and lens capsule (3 and 4). The capsulotomy pattern (5) and lens segmentation pattern (6) are shown in solid red.” Figure 3B is a “[v]iew of the eye in the near-infrared video camera, with overlaid guidance lines indicating a planned capsulotomy pattern (1) and a boundary of the pupil (2).”

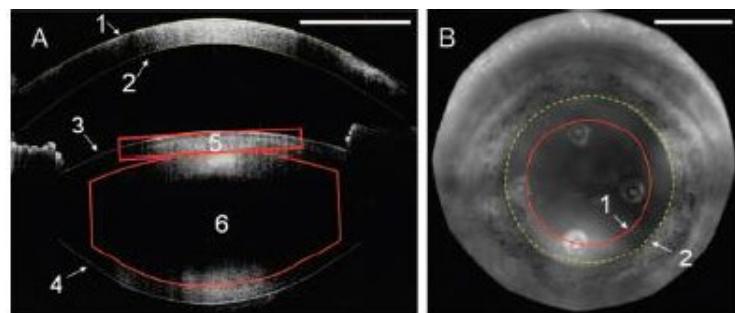


Figure 3C is a “[t]op view of the circular capsulotomy pattern, a cross-pattern for lens segmentation, and the nucleus fragmentation pattern.”

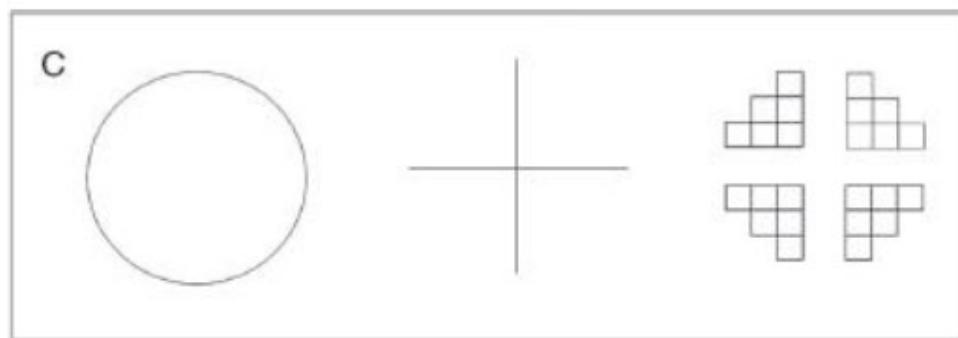


Figure 3D is a “[t]hree-dimensional representation of the capsulotomy and cross-segmentation patterns in the lens alone (left) and inside the eye (right).”



466. Further, the '539 patent discloses “[t]he shared optics 50 under the control of the control electronics 54 can automatically generate aiming, ranging, and treatment scan patterns. Such patterns can be comprised of a single spot of light, multiple spots of light, a continuous pattern of light, multiple continuous patterns of light, and/or any combination of these.” “The positioning and character of the laser pulse beam 66 and/or the scan pattern the laser pulse beam 66 forms on the eye 43 may be further controlled by use of an input device....” The '539 patent states “[t]he ranging subsystem 46 is configured to measure the spatial disposition of eye structures in three dimensions” and “information may then be loaded into the laser 3-D scanning system or used to generate a three dimensional model/representative/image of the cornea, anterior chamber, and lens of the eye, and used to define the cutting patterns used in the surgical procedure.” The 2018 CATALYS® brochure describes accounting for the lens tilt:

TITLED LENS WITH TILT MANAGEMENT
The CATALYS® System detects lens tilt and adjusts the safety zone accordingly.

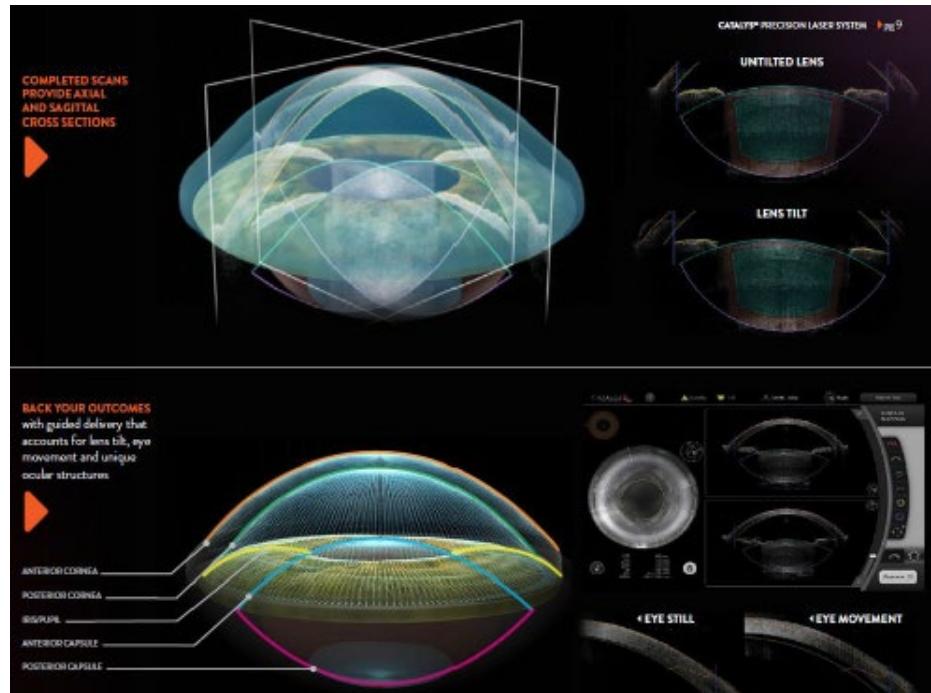
The diagram shows a cross-section of an eye with a tilted lens. A dashed circle indicates the iris safety margin, labeled as 500 µm. The text "ENTIRE LENS IS OPTIMALLY FRAGMENTED" is at the bottom.

3D OCT IMAGING

- Identifies anterior cornea, posterior cornea, iris, anterior lens and posterior lens
- Performs > 10,000 A-scans to capture high-resolution data for the full volume of the anterior segment
- Displays axial and sagittal cross sections from completed scans
- Refreshes at 0.5–2.0 Hz for real-time visualization of the eye throughout treatment

INTEGRAL GUIDANCE TECHNOLOGY

- Generates accurate pictures of the anterior chamber using 3D OCT imaging data
- Maps incision orientation and depth based on the treatment plan
- Provides safety zones that adapt for lens tilt to maximize lens fragmentation volume



467. CATALYS® includes an imaging-based laser-controller, configured to cause the beam scanner to scan the beam of laser pulses to the points of the cylindrical scan-pattern. The '539 patent discloses “the shared optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Further, the '539 patent discloses that “[u]sing the assembly 62, optical beam can be scanned in the patient’s eye” and the laser “can be focused into eye tissue … to cause photodisruption around the focal point.” Figure 3 discloses the components of the shared optics, including the Z-Tscope. The '539 patent discloses “[f]ollowing the beam combiner 82, the laser pulse beam 66 continues through a Z-telescope 84, which is operable to scan focus position of the laser pulse beam 66 in the patient’s eye 43 along the Z axis.... In this way, the focus position of the spot in the patient’s eye 43 moves along the Z axis.” Further, “[t]he motion can be nonlinear and directed via a model or a calibration from measurement or a combination of both.” “The Z-telescope 84 functions as z-scan device for scanning the focus point of the laser-pulse beam 66 in the patient’s eye 43. The Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The '539 patent discloses that the “X-scan device” and “Y-scan device” are “controlled by the control electronics 54” and “[m]odeling or calibrated

measurement of the relationship or combination of both can be determined and used to direct the location of the beam.” The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” The User Manual states “Pattern-Circular is the only pattern option”, the incision depth is the “axial extent of capsulotomy cylinder pattern, centered around the detected lens anterior surface,” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” See also <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=-FcUGyzVLE8&feature=emb_logo.

468. CATALYS® includes an imaging-based laser-controller, configured to cause the beam attenuator to control the laser-power parameter of the laser pulses such that a laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold. The '539 patent discloses that “[u]sing the assembly 62, optical beams can be scanned in the patient's eye 43

in three dimensions: X, Y, Z...short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.”

469. The CATALYS® system meets each and every limitation of at least claim 1 of the ’913 patent, either literally and/or under the doctrine of equivalents.

470. AMO Accused Infringers’ manufacture, use, offer to sell, and sale of CATALYS® in the United States infringe the ’913 patent under 35 U.S.C. § 271(a).

471. AMO Accused Infringers’ customers in the United States also directly infringe the ’913 patent by using CATALYS®. AMO Accused Infringers actively induce infringement of the ’913 patent by encouraging their customers to use CATALYS®, with knowledge that the induced acts constitute patent infringement and/or with willful blindness to infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, AMO Accused Infringers’ inducing acts include marketing CATALYS®, supporting the ongoing use of CATALYS® by providing

consumables for use with CATALYS®, and providing installation, maintenance, service, and/or repair of CATALYS®. Additionally, upon information and belief, AMO Accused Infringers publish and provide product documentation and educational materials that instruct and encourage their customers to use CATALYS® in an infringing manner. For example, upon information and belief, AMO Accused Infringers warn customers in the 2019 User Manual for CATALYS® that “[t]o protect operating personnel and patients, this manual should be read thoroughly and understood before operation.”

472. AMO Accused Infringers have known of the '913 patent and of their infringement prior to this litigation, at least since May 2020 pursuant to Alcon Patent Plaintiffs' notice letter identifying the '913 patent and AMO Accused Infringers' infringement thereof. AMO Accused Infringers nevertheless have continued inducing infringement.

473. AMO Accused Infringers are not licensed under the '913 patent.

474. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through the marking of LenSx®.

475. Thus, AMO Accused Infringers' manufacture, use, offer to sell, sale, and export of CATALYS® in or from the United States infringe at least claim 1 of the '913 patent under 35 U.S.C. § 271(a)-(c).

476. Alcon Patent Plaintiffs will suffer damage as a direct and proximate result of AMO Accused Infringers' infringement of the '913 patent. Thus, Alcon Patent Plaintiffs are entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

477. Alcon Patent Plaintiffs have been damaged and will continue to be damaged by AMO Accused Infringers' infringement of the '913 patent.

478. Alcon Patent Plaintiffs have suffered and will suffer irreparable harm unless and until AMO Accused Infringers' infringing activities are enjoined by this Court. Alcon Patent Plaintiffs do not have an adequate remedy at law.

COUNT XXXVI

(Infringement of U.S. Patent No. 9,456,925)

479. Alcon Patent Plaintiffs incorporate by reference the allegations in paragraphs 1 through 478.

480. U.S. Patent No. 9,456,925 ("the '925 patent"), entitled "Photodisruptive Laser Treatment of the Crystalline Lens," was duly and legally issued by the USPTO on October 4, 2016. The named inventors on the '925 patent are Ronald Kurtz, Ferenc Raksi, and Peter Goldstein. A true and correct copy of the '925 patent is attached to this Complaint as Exhibit 5.

481. Alcon Inc. and Alcon Research are the owners of the '925 patent and have the full right to enforce, license, and seek past damages for the '925 patent.

482. Alcon Research was the exclusive licensee of the '925 patent.

483. Alcon Vision is the exclusive licensee of the '925 patent.

484. The '925 patent is valid and enforceable.

485. Alcon Patent Plaintiffs' '925 patent, including at least claim 1, is directed to a method of treating a crystalline lens of an eye with a laser. Generally, this patent is directed to treating the hard lens region of an eye with a laser to enable easier removal of the lens. A laser performs a photodisruptive procedure, creating bubbles to break up the lens. The laser bubbles can be applied to form incisions of specific dimensions and orientations

486. Claim 1 of the '925 patent recites:

1. A method of treating a crystalline lens of an eye with a laser, the method comprising:

selecting a surgical region of the lens; and

forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics along a curved focal plane of the laser delivery optics to form a line of bubbles in each layer without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner, wherein:

an orientation of a portion of the incisions is one of an orientation intersecting fibers of the lens and an orientation non-transverse to an axis of the eye; and

the incision has a spatial extent in a Z direction in the range of 0.5-10 mm, and in an X-Y plane in the range of 2-10 mm.

487. CATALYS® performs a method of treating a crystalline lens of an eye with a laser. The 2018 CATALYS® brochure discloses “[t]he OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single-plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.” *See also* 2019 User Manual. *See also* JJSV website, <https://www.jnjvisionpro.com/products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”)

488. CATALYS® performs a method including selecting a surgical region of the lens. The 2019 User Manual instructs “[a]fter verifying surface fits, press the APPROVE button on the Surface Mapping Review Screen (all surfaces view) to go to the Incision Review Screens. From the Incision Review Screens, you can:

- Review and verify treatment parameters
- View streaming updates of section scans
- Suppress individual incisions
- Navigate to the Incision Adjustment Screens to adjust treatment parameters.”

Further, “[w]hen satisfied with the INTEGRAL GUIDANCE System treatment customization, press the APPROVE button on the Surface Mapping Review Screen (all surfaces view) to go to the Incision Review Screens.”

Figure 4.40 Incision Review Screen

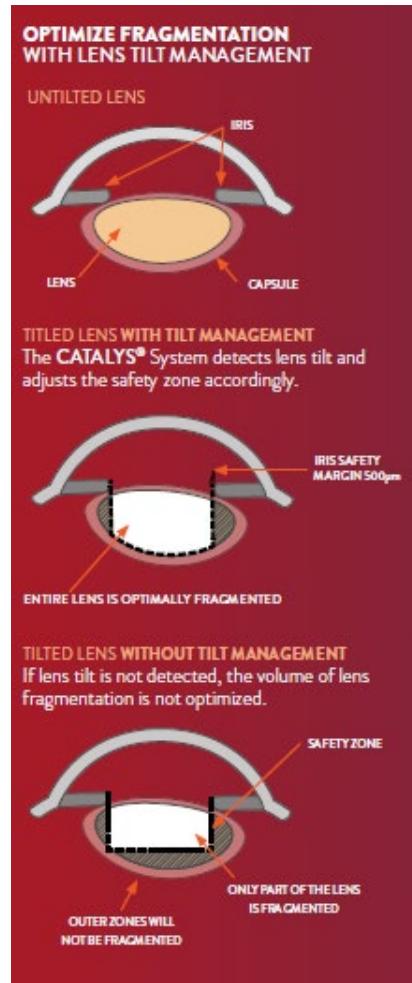


It also discloses “Review the treatment parameters on the Final Review Screen. If desired, press the BACK button to return to the Incision Review Screen(s). Otherwise, start laser treatment, as described in the following section.”

Figure 4.42 Final Review Screen and Start Treatment



489. CATALYS® performs a method including forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics along a curved focal plane of the laser delivery optics to form a line of bubbles in each layer without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner. The 2018 CATALYS® brochure discloses that “[t]he CATALYS® System detects lens tilt and adjusts the safety zone accordingly” such that the “entire lens is optimally fragmented” along a curved focal plane:



The '539 patent discloses “[t]he cutting laser subsystem 44 includes an ultrafast (UF) laser 64 (e.g., a femtosecond laser),” and the “short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” Further, CATALYS® does not adjust the Z scanner of the laser delivery optics at a scanning rate of the XY scanner. The '539 patent discloses “the shared optics 50 includes scanning mechanisms operable to scan the respective emission in three dimensions.” “For example, the

shared optics can include an XY-scan mechanism(s) and a Z-scan mechanism.” “The Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Figure 3 discloses the components of the shared optics, including the Z-Tscope. The ’539 patent discloses “[f]ollowing the beam combiner 82, the laser pulse beam 66 continues through a Z-telescope 84, which is operable to scan focus position of the laser pulse beam 66 in the patient’s eye 43 along the Z axis.... In this way, the focus position of the spot in the patient’s eye 43 moves along the Z axis.” Further, “[t]he motion can be nonlinear and directed via a model or a calibration from measurement or a combination of both.” “The Z-telescope 84 functions as z-scan device for scanning the focus point of the laser-pulse beam 66 in the patient’s eye 43. The Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54....” The ’539 patent discloses that the “X-scan device” and “Y-scan device” are “controlled by the control electronics 54” and “[m]odeling or calibrated measurement of the relationship or combination of both can be determined and used to direct the location of the beam.” Further, the User Manual discloses the safety margins:

Figure 4.4 Iris Safety Margins for Lens Fragmentation – Axial and Sagittal Views

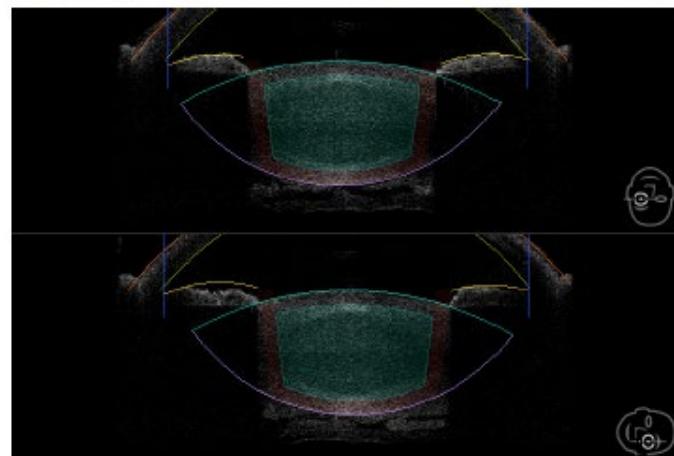
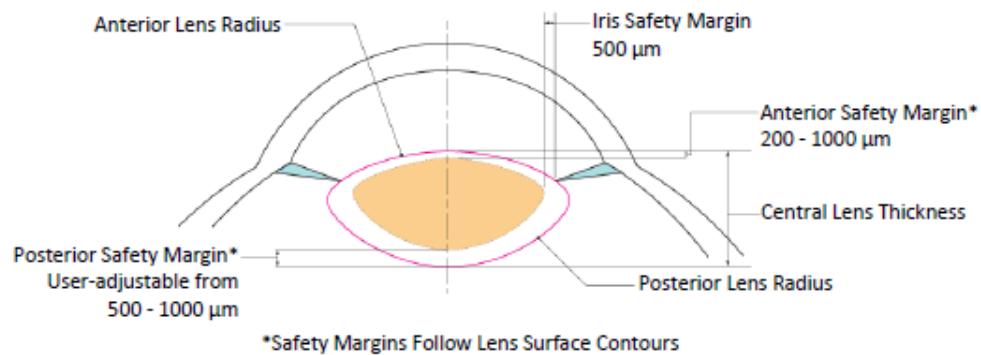


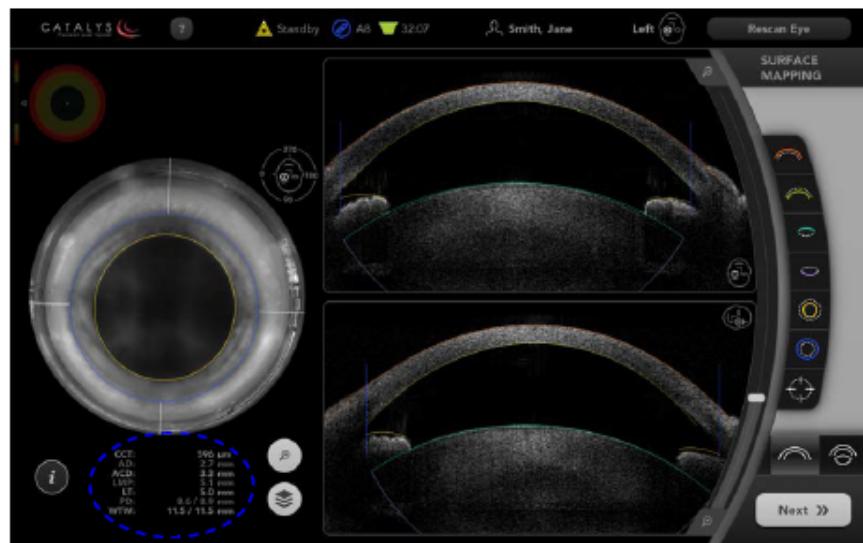
Figure 4.5 Safety Margin for Lens Fragmentation



Cross-sectional view highlighting geometric relationships of lens radius (shown in red); lens fragmentation pattern (shown in orange); and respective safety margins for the iris and anterior and posterior lens radii.

The 2019 User Manual also discloses the following measurements are taken along a vector orthogonal to the tilt of the lens:

Figure 3.94 Location of INTEGRAL GUIDANCE System Dimensions



The following measurements are taken along a vector orthogonal to the tilt of the lens:

- CCT (central cornea thickness)—distance between anterior and posterior cornea
- AD (aqueous depth)—distance between posterior cornea and anterior lens
- ACD (anterior chamber depth)—distance between anterior cornea and anterior lens
- LMP (lens meridian position)—distance from anterior cornea to lens equator (i.e., intersection of lens anterior and lens posterior surface maps)
- LT (lens thickness)—distance from lens anterior to lens posterior
- PD (pupil diameter)—pupil diameter including minor and major axis
- WTW (white to white)—limbus diameter including minor and major axis

490. CATALYS® performs a method including wherein: an orientation of a portion of the incisions is one of an orientation intersecting fibers of the lens and an orientation non-transverse to an axis of the eye. The User Manual states “Pattern-Circular is the only pattern option,” the incision depth the “axial extent of capsulotomy cylinder pattern, centered around the detected lens anterior surface,” and the “Scanned Capsule—uses the INTEGRAL GUIDANCE System data for the anterior and posterior lens surfaces, and the line connecting the centers of the spheres fitted to these surfaces, to center the capsulotomy.” See also <https://youtube.com/watch?v=4TaEcrBAzCI>; https://www.youtube.com/watch?time_continue=69&v=

FcUGyzVLE8&feature=emb_logo. Further, the User Manual discloses the incisions made during the procedure:

Figure 3.63 Arcuate Incisions Details Screen



From the Arcuate Incisions Details Screen, you can select the following parameters:

- Penetration Type
 - Anterior Penetrating—has uncut region in posterior cornea
 - Intrastromal—has uncut regions in anterior and posterior cornea
- Depth Unit (Percent or Microns)—uncut tissue depth at a given location in the cornea
- Uncut Anterior/Posterior Percentage or Microns
- Side Cut Angle—angle at which incision is made with respect to the anterior cornea at location of incision
- Horizontal Spot Spacing—lateral spot-to-spot spacing
- Vertical Spot Spacing—axial spot-to-spot spacing
- Pulse Energy—energy delivered per pulse
- Anterior/Central Line Density—spacing between successive lines of the incision. For arcuate incisions, the line density can be independently defined for the anterior and central regions of the incision. Refer to [Figure 4.11 Line Density Characteristics](#) on page 172 for a graphic representation of line density.
- Anterior Line Distance—region that line density is applied to the respective cut segment, measured in microns or percentage of corneal thickness, depending on Depth Unit setting; used to adjust the spot spacing from the anterior portion of the incision to the central portion of the incision. For example, if the anterior line distance is 30%, the anterior-most 30% of the corneal thickness will be at the anterior line density and the remaining portion of the arcuate incision will be at central line density.

Figure 3.65 Cataract Incisions Primary Geometric Details Screen



From the Cataract Incisions Primary Geometric Details Screen, you can select the following parameters:

- Uncut Region (Anterior, Central, Posterior, or None)
- Depth Unit (Percent or Microns)
- Uncut Anterior/Posterior Percentage or Microns
- Uncut Central Length
- Anterior/Posterior Plane Depth
- Anterior/Posterior Side Cut Angle

Treatment Plan Summary Screen

After you have selected the desired treatment parameters, press the NEXT button on the (Basic) or Details Screen for the last treatment in the sequence to proceed to the Treatment Plan Summary Screen. You can also navigate to the Treatment Plan Summary Screen by pressing the Quick Navigation Bar Treatment Plan Summary Icon on the Patient Info, Capsulotomy, Lens Fragmentation, Arcuate Incisions, or Cataract Incisions Screen. The Treatment Plan Summary Screen provides an overview of the current treatment plan, including a graphical representation of the selected treatment parameters.

Figure 3.69 Treatment Plan Summary Screen



Figure 3.95 Capsulotomy Incision Review Screen

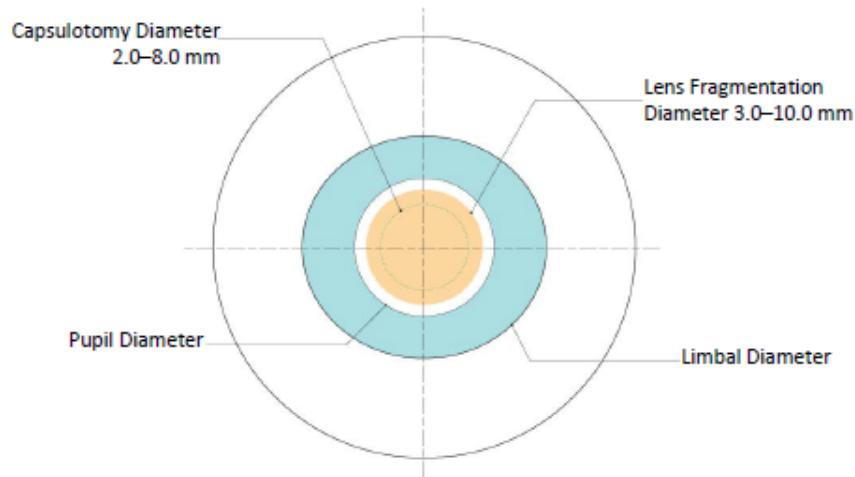


491. CATALYS® performs a method including wherein the incision has a spatial extent in a Z direction in the range of 0.5-10 mm, and in an X-Y plane in the range of 2-10 mm. The 2019 User Manual discloses the following incisions:

Capsulotomy Parameters

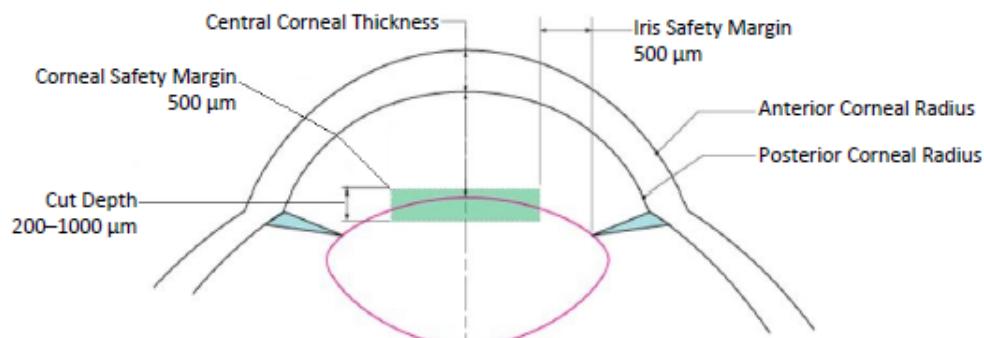
Capsulotomy parameters, including cut dimensions, laser settings, and applicable safety margins, are illustrated in the following figures and summarized in the following tables.

Figure 4.1 Relationships of Key Anatomical Diameters



Concentric, geometric relationship of the pupil (bottom left) and limbus (bottom right) shown in blue shading; capsulotomy diameter (top left) shown by dotted line within orange shading; and lens fragmentation diameter (top, right) shown in orange shading.

Figure 4.2 Corneal and Iris Safety Margins

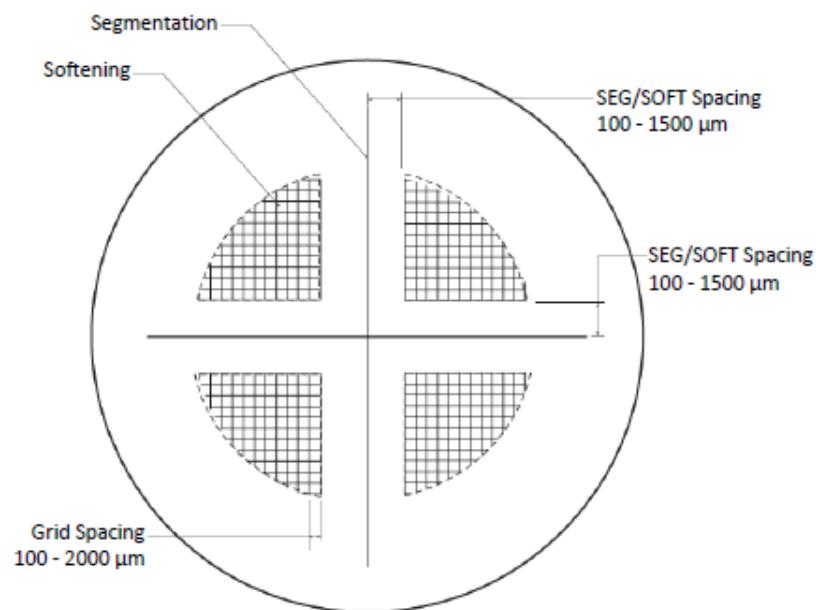


Cross-sectional view highlighting geometric relationships of lens (shown in red) and respective safety margins for iris and cornea.

Table 4.1 User-adjustable Capsulotomy Parameters

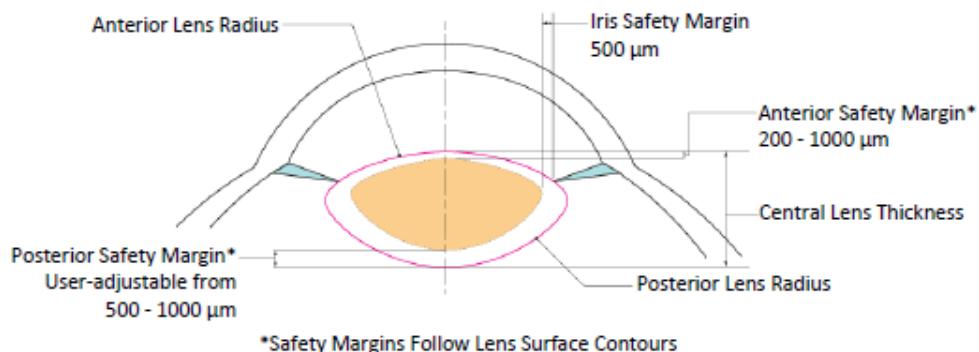
Feature	Default	Range	Step Size	Units
Pattern	Circle	N/A	N/A	N/A
Depth	600	200-1000	200	μm
Diameter	N/A	2.0-8.0	0.1	mm
Horizontal Spot Spacing	5	3-10	1	μm
Vertical Spot Spacing	10	5-50	5	μm
Laser Pulse Energy	4	1-10	0.5	μJ

Figure 4.3 Lens Fragmentation Patterns



SEG/SOFT denotes distance between segmentation and softening. Incremental spacing is available for each parameter, as shown.

Figure 4.5 Safety Margin for Lens Fragmentation



Cross-sectional view highlighting geometric relationships of lens radius (shown in red); lens fragmentation pattern (shown in orange); and respective safety margins for the iris and anterior and posterior lens radii.

Table 4.3 User-adjustable Lens Fragmentation Parameters

Feature	Default	Range	Step Size	Units
Diameter	N/A ^a	3.0-10.0	0.5	mm
Horizontal Spot Spacing	10	5-25	2.5	μm
Vertical Spot Spacing	40	10-100	10	μm
Pulse Energy, Anterior ^b	8	1-10	0.5	μJ
Pulse Energy, Posterior ^b	10	1-10	0.5	μJ
Seg-Soft Spacing	200	100-1500	100	μm
Grid Spacing	350	100-2000	100	μm

a. Default diameter is defined by available pupil diameter (less 2 x safety margin).

b. Pulse energy to vary stepwise (linear) from posterior to anterior, if different.

492. Thus, use of the CATALYS® system meets each and every limitation of at least claim 1 of the '925 patent, either literally and/or under the doctrine of equivalents.

493. AMO Accused Infringers' testing and use of CATALYS® in the United States infringe the '925 patent under 35 U.S.C. § 271(a).

494. AMO Accused Infringers' customers in the United States also directly infringe the '925 patent by using CATALYS®. AMO Accused Infringers actively induce infringement of the '925 patent by encouraging their customers to use

CATALYS®, with knowledge that the induced acts constitute patent infringement and/or with willful blindness to infringement, in violation of 35 U.S.C. § 271(b). Upon information and belief, AMO Accused Infringers' inducing acts include marketing CATALYS®, supporting the ongoing use of CATALYS® by providing consumables for use with CATALYS®, and providing installation, maintenance, service, and/or repair of CATALYS®. Additionally, upon information and belief, AMO Accused Infringers publish and provide product documentation and educational materials that instruct and encourage their customers to use CATALYS® in an infringing manner. For example, upon information and belief, AMO Accused Infringers warn customers in the 2019 User Manual for CATALYS® that “[t]o protect operating personnel and patients, this manual should be read thoroughly and understood before operation.”

495. AMO Accused Infringers have known of the '925 patent and of their infringement prior to this litigation, at least since May 2020 pursuant to Alcon Patent Plaintiffs' notice letter identifying the '925 patent and AMO Accused Infringers' infringement thereof. AMO Accused Infringers nevertheless have continued inducing infringement.

496. AMO Accused Infringers also contribute to infringement of the patent by offering to sell and selling CATALYS®, in violation of 35 U.S.C. § 271(c). The CATALYS® system is an apparatus for use in practicing the patented process.

AMO Accused Infringers supply customers with the CATALYS® system knowing it is especially made and especially adapted for a use that infringes the patent. The customer necessarily infringes the patent when it uses CATALYS® for the indicated use in patients undergoing cataract surgery. See JJSV website, <https://www.jnjvisionpro.com /products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”). AMO Accused Infringers specifically list “intended uses in cataract surgery” and do not market CATALYS® for LASIK surgery. *Id.* CATALYS® is not a staple article or commodity of commerce, and it does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use CATALYS® for the indicated uses in a way to avoid infringement of the patent.

497. AMO Accused Infringers are not licensed under the ’925 patent.

498. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through the marking of LenSx®.

499. Thus, AMO Accused Infringers’ manufacture, use, offer to sell, sale, and export of CATALYS® in or from the United States infringe at least claim 1 of the ’925 patent under 35 U.S.C. § 271(a)-(c).

500. Alcon Patent Plaintiffs will suffer damage as a direct and proximate result of AMO Accused Infringers' infringement of the '925 patent. Thus, Alcon Patent Plaintiffs are entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

501. Alcon Patent Plaintiffs have been damaged and will continue to be damaged by AMO Accused Infringers' infringement of the '925 patent.

502. Alcon Patent Plaintiffs have suffered and will suffer irreparable harm unless and until AMO Accused Infringers' infringing activities are enjoined by this Court. Alcon Patent Plaintiffs do not have an adequate remedy at law.

COUNT XXXVII

(Infringement of U.S. Patent No. 9,427,356)

503. Alcon Patent Plaintiffs incorporate by reference the allegations in paragraphs 1 through 502.

504. U.S. Patent No. 9,427,356 ("the '356 patent"), entitled "Photodisruptive Laser Fragmentation of Tissue," was duly and legally issued by the USPTO on August 30, 2016. The named inventor on the '356 patent is Ferenc Raksi. A true and correct copy of the '356 patent is attached to this Complaint as Exhibit 6.

505. Alcon Inc. and Alcon Research are the owners of the '356 patent and have the full right to enforce, license, and seek past damages for the '356 patent.

506. Alcon Research was the exclusive licensee of the '356 patent.

507. Alcon Vision is the exclusive licensee of the '356 patent.

508. The '356 patent is valid and enforceable.

509. Alcon Patent Plaintiffs' '356 patent, including at least claim 1, is directed to a method of fragmenting lens tissue of an eye with a laser surgical system. Generally, this patent is directed to a method of photodisruptive laser surgery that includes selecting a target region of a tissue for fragmentation, directing a beam of laser pulses to the selected target region of the tissue, and forming a regular array of cells in the target region of the tissue by directing the laser beam to generate cell boundaries for more precise control over the photodisruption. The layers of photodisrupted cells track the natural curvature of the lens.

510. Claim 1 of the '356 patent recites:

1. A method of fragmenting lens tissue of an eye with a laser surgical system, the method comprising:

generating a pulsed laser beam with a pulsed laser;

directing the laser beam with an optics module towards a target region in the lens tissue; and

controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries, wherein

the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens.

511. CATALYS® performs a method of fragmenting lens tissue of an eye with a laser surgical system. The 2019 User Manual discloses that “[t]he OPTIMEDICA CATALYS® Precision Laser System is an integrated scanning laser system that is used by cataract surgeons to create a precise anterior capsulotomy and/or subsequent fragmentation (phacofragmentation) of the crystalline lens, with or without single plane and multi-plane arc cuts/incisions in the cornea. Treatment is accomplished through the use of ultrafast ($\tau \sim 10\text{-}13\text{s}$, or hundreds of femtoseconds [FS]) infrared laser pulses.” See also JJSV website, <https://www.jnjvisionpro.com/products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”) The User Manual also discloses that “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” OCT data guides the incisions and the optical subsystems include dedicated electronics. See User Manual; ’539 patent.

512. CATALYS® performs a method including generating a pulsed laser beam with a pulsed laser. The 2019 User Manual discloses “[t]reatment is

accomplished through the use of ultrafast ($\tau \sim 10\text{-}13\text{s}$, or hundreds of femtoseconds [FS]) infrared laser pulses.” The ’539 patent discloses “[t]he cutting laser subsystem 44 includes an ultrafast (UF) laser 64 (e.g., a femtosecond laser).... For example, short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” Further, publications describe CATALYS® including a pulse frequency of 120 KHz. *See* Donaldson KE, et al., Femtosecond laser-assisted cataract surgery, JC RS. 013;39:1753-1763.

513. CATALYS® performs a method including directing the laser beam with an optics module towards a target region in the lens tissue. The ’539 patent discloses “short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” Further, the 2019 User Manual discloses “[t]he OPTIMEDICA CATALYS® Precision Laser System is an integrated scanning laser system that is used by cataract surgeons to create a precise anterior capsulotomy and/or subsequent fragmentation (phacofragmentation) of the crystalline lens.... The on-board Optical Coherence Tomography (OCT) subsystem provides a three-dimensional image of the anterior segment of the eye and guides laser treatment.” Further “[t]he treatment

consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” The User Manual states “[t]he CATALYS® System consists of three integrated optical subsystems, each controlled and monitored by dedicated electronics.”

514. CATALYS® performs a method including controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries. The system guides the laser based on the OCT data. *See* '539 patent; User Manual. Further, the 2019 User Manual discloses that the laser patterns generate a regular array of cells in the target region:

Lens Fragmentation Parameters

Lens Fragmentation parameters, including cut dimensions for lens segmentation and softening, laser settings, and applicable safety margins, are illustrated in the following figures and summarized in the following tables.

Patterns	Description
	Lens Segmentation: Quadrants (2 intersecting lines)
	Lens Segmentation: Sextants (3 intersecting lines)
	Lens Segmentation: Octants (4 intersecting lines)
	Lens Softening: Quadrants
	Lens Softening: Sextants
	Lens Softening: Octants
	Quadrants Complete

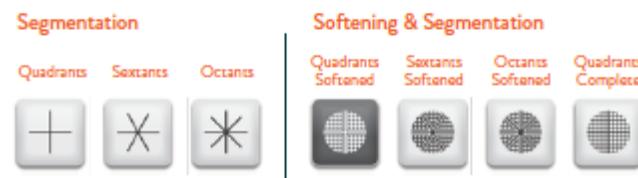
The 2018 CATALYS® brochure similarly discloses the fragmentation options:

POWERFULLY EFFECTIVE FRAGMENTATION

- Complete softening and segmentation⁷
- Optimized fragmentation volume with automatic lens tilt management
- Multiple fragmentation patterns
- High-quality fragmentation, even in dense cataracts^{8*}

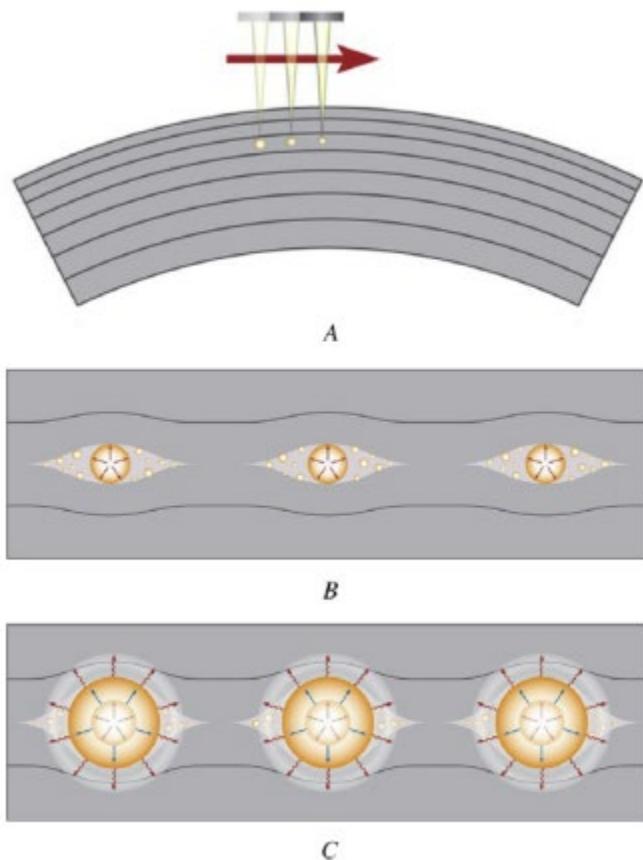
CUSTOMIZABLE FRAGMENTATION OPTIONS,

with an adjustable softening grid for complete softening and segmentation⁷



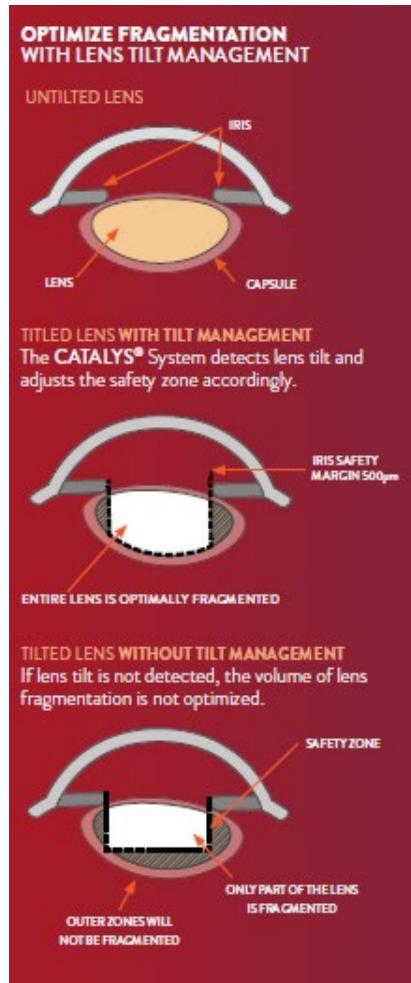
The '539 patent discloses “short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption

around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma” and the bubbles of photodisruption form in layers. See User Manual; ’539 patent. The layers of photodisruption are further disclosed in publications. See e.g., Donaldson KE, et al., Femtosecond laser-assisted cataract surgery, JCRS. 013;39:1753-1763 (shown below).



515. CATALYS® performs a method including wherein the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens. The system guides the laser based on the OCT data based on a curved focal plane. The

2019 User Manual discloses “[t]he OPTIMEDICA CATALYS® Precision Laser System is an integrated scanning laser system that is used by cataract surgeons to create a precise anterior capsulotomy and/or subsequent fragmentation (phacofragmentation) of the crystalline lens.... The on-board Optical Coherence Tomography (OCT) subsystem provides a three-dimensional image of the anterior segment of the eye and guides laser treatment.” Further “[t]he treatment consists of applying user-defined laser patterns to the crystalline lens, lens capsule, and cornea of the eye to create incisions by applying FS laser pulses, guided by the OCT data.” “Intended treatment patterns are overlaid on streaming cross-sectional OCT images of the anterior segment for review before the physician allows treatment to begin.” The User Manual states “[t]he CATALYS® System consists of three integrated optical subsystems, each controlled and monitored by dedicated electronics.” Further, the 2018 CATALYS® brochure discloses that “[t]he CATALYS® System detects lens tilt and adjusts the safety zone accordingly” such that the “entire lens is optimally fragmented” along a curved focal plane:



The '539 patent discloses the “short-pulsed laser light generated by the UF laser 64 can be focused into eye tissue to produce dielectric breakdown to cause photodisruption around the focal point (the focal zone), thereby rupturing the tissue in the vicinity of the photo-induced plasma.” Further, “[t]he Z-scan mechanism can be used to vary the depth of the focal point within the eye 43.” Figure 3 discloses the components of the shared optics, including the Z-Tscope. The '539 patent discloses “[f]ollowing the beam combiner 82, the laser pulse beam 66 continues through a Z-telescope 84, which is operable to scan focus position of the laser pulse

beam 66 in the patient's eye 43 along the Z axis.... In this way, the focus position of the spot in the patient's eye 43 moves along the Z axis." Further, "[t]he motion can be nonlinear and directed via a model or a calibration from measurement or a combination of both." "The Z-telescope 84 functions as z-scan device for scanning the focus point of the laser-pulse beam 66 in the patient's eye 43. The Z-telescope 84 can be controlled automatically and dynamically by the control electronics 54...." The '539 patent discloses that the "X-scan device" and "Y-scan device" are "controlled by the control electronics 54" and "[m]odeling or calibrated measurement of the relationship or combination of both can be determined and used to direct the location of the beam."

516. Thus, use of the CATALYS® system meets each and every limitation of at least claim 1 of the '356 patent, either literally and/or under the doctrine of equivalents.

517. AMO Accused Infringers' use and testing of CATALYS® in the United States infringe the '356 patent under 35 U.S.C. § 271(a).

518. AMO Accused Infringers' customers in the United States also directly infringe the '356 patent by using CATALYS®. AMO Accused Infringers actively induce infringement of the '356 patent by encouraging their customers to use CATALYS®, with knowledge that the induced acts constitute patent infringement and/or with willful blindness to infringement, in violation of 35 U.S.C. § 271(b).

Upon information and belief, AMO Accused Infringers' inducing acts include marketing CATALYS®, supporting the ongoing use of CATALYS® by providing consumables for use with CATALYS®, and providing installation, maintenance, service, and/or repair of CATALYS®. Additionally, upon information and belief, AMO Accused Infringers publish and provide product documentation and educational materials that instruct and encourage their customers to use CATALYS® in an infringing manner. For example, upon information and belief, AMO Accused Infringers warn customers in the 2019 User Manual for CATALYS® that “[t]o protect operating personnel and patients, this manual should be read thoroughly and understood before operation.”

519. AMO Accused Infringers have known of the '356 patent and of their infringement prior to this litigation, at least since May 2020 pursuant to Alcon Patent Plaintiffs' notice letter identifying the '356 patent and AMO Accused Infringers' infringement thereof. AMO Accused Infringers nevertheless have continued inducing infringement.

520. AMO Accused Infringers also contribute to infringement of the patent by offering to sell and selling CATALYS®, in violation of 35 U.S.C. § 271(c). The CATALYS® system is an apparatus for use in practicing the patented process. AMO Accused Infringers supply customers with the CATALYS® system knowing it is especially made and especially adapted for a use that infringes the patent. The

customer necessarily infringes the patent when it uses CATALYS® for the indicated use in patients undergoing cataract surgery. See JJSV website, <https://www.jnjvisionpro.com/products/catalys%C2%AE-precision-laser-system> (accessed Sept. 8, 2020) (“The OptiMedica® CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.”). AMO Accused Infringers specifically list “intended uses in cataract surgery” and do not market CATALYS® for LASIK surgery. *Id.* CATALYS® is not a staple article or commodity of commerce, and it does not have a substantial noninfringing use. Upon information and belief, customers have no practical ability to modify or use CATALYS® for the indicated uses in a way to avoid infringement of the patent.

521. AMO Accused Infringers are not licensed under the ’356 patent.

522. The marking requirement of 35 U.S.C. § 287(a) has been satisfied through the marking of LenSx®.

523. Thus, AMO Accused Infringers’ manufacture, use, offer to sell, sale, and export of CATALYS® in or from the United States infringe at least claim 1 of the ’356 patent under 35 U.S.C. § 271(a)-(c).

524. Alcon Patent Plaintiffs will suffer damage as a direct and proximate result of AMO Accused Infringers’ infringement of the ’356 patent. Thus, Alcon

Patent Plaintiffs are entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

525. Alcon Patent Plaintiffs have been damaged and will continue to be damaged by AMO Accused Infringers' infringement of the '356 patent.

526. Alcon Patent Plaintiffs have suffered and will suffer irreparable harm unless and until AMO Accused Infringers' infringing activities are enjoined by this Court. Alcon Patent Plaintiffs do not have an adequate remedy at law.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Alcon Patent Plaintiffs hereby respectfully request a jury trial on all issues and claims so triable.

PRAYER FOR RELIEF

WHEREFORE, for its Patent Counterclaims, Alcon Patent Plaintiffs request the following judgments and relief against AMO Accused Infringers :

- (vii) A judgment that AMO Accused Infringers have infringed each of the Alcon Asserted Patents;
- (viii) A judgment that enjoins AMO Accused Infringers and their officers, agents, servants, and employees from further infringement of the Alcon Asserted Patents.
- (ix) An award of all damages adequate to compensate Alcon Patent Plaintiffs for AMO Accused Infringers' infringement of the Alcon

Asserted Patents, such damages to be determined by a jury, and an accounting;

- (x) An award of pre-judgment and post-judgment interest at the maximum rate allowed by law;
- (xi) That a judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285, and accordingly that Alcon Patent Plaintiffs are entitled to recover reasonable attorneys' fees and costs upon prevailing in this action; and
- (xii) That Alcon Patent Plaintiffs be awarded such other relief that the Court deems just and equitable, or which the Court deems just and proper.

Respectfully,

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Dated: January 18, 2022

CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on January 18, 2022, this document was served on the persons listed below in the manner indicated:

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EXHIBIT 1

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May 11, 2020

Mr. Warren Foust
Johnson & Johnson Surgical Vision, Inc.
1700 St. Andrew Place
Santa Ana, CA 92705

Re: Notice of Dispute under Confidential Settlement Agreement dated June 30, 2006

Dear Mr. Foust:

I write on behalf of Alcon Inc. and its affiliates as successor to Alcon, Inc., Alcon Laboratories, Inc., and Alcon Manufacturing, Ltd. (collectively, "Alcon") to Johnson & Johnson Surgical Vision, Inc. ("JJSVI") as successor to the obligations of Advanced Medical Optics, Inc. ("AMO") pursuant to the Confidential Settlement Agreement between AMO and Alcon effective June 30, 2006 ("Agreement") (attached).

This letter serves to notify JJSVI of a dispute under Section VII of the Agreement. The manufacture, use, sale, offer for sale, and/or importation of the Catalys Precision Laser System by JJSVI and/or its affiliates (including, without limitation, AMO Development, LLC, Johnson & Johnson Vision Care, Inc., Johnson & Johnson Vision Care (Ireland), and JJ Surgical Vision Spain, S.L.) appears to directly and/or indirectly infringe one or more claims of the following patents:

US	8,398,236	Image-Guided Docking For Ophthalmic Surgical Systems
US	8,764,737	Precise Targeting of Surgical Photodisruption
US	9,044,303	Precise Targeting of Surgical Photodisruption
US	9,408,749	Precise Targeting of Surgical Photodisruption
US	9,427,356	Photodisruptive Laser Fragmentation of Tissue

6201 South Freeway
Fort Worth, Texas 76134-2099

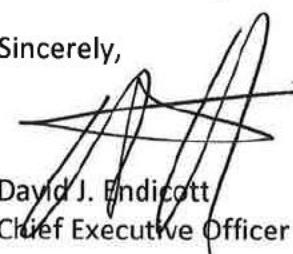


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US	9,456,925	Photodisruptive Laser Treatment of the Crystalline Lens
US	9,622,913	Imaging-Controlled Laser Surgical System
US	9,849,036	Imaging-Controlled Laser Surgical System
EP	2 240 108	Photodisruptive Laser Fragmentation of Tissue
EP	2 579 827	Image-Guided Docking For Ophthalmic Surgical Systems
EP	2 826 436	Precise Targeting of Surgical Photodisruption
EP	2 926 780	Photodisruptive Laser Fragmentation of Tissue

Pursuant to the Agreement, we look forward to engaging in negotiations with you or your designated counterpart to try to amicably resolve this dispute within the 21-day period set out in Section 7.1 of the Agreement. If the parties do not amicably resolve the dispute during that period, we intend to include it in the mediation the parties are currently working to schedule in June 2020.

Sincerely,



David J. Endicott
Chief Executive Officer

Attachment

cc: Michael Ullmann, Executive Vice President, General Counsel, Johnson & Johnson
Denise DeFranco, Global Head, IP Litigation, Johnson & Johnson

EXHIBIT 2



US008398236B2

(12) United States Patent
Juhasz et al.(10) Patent No.: US 8,398,236 B2
(45) Date of Patent: Mar. 19, 2013

(54) IMAGE-GUIDED DOCKING FOR OPHTHALMIC SURGICAL SYSTEMS

(75) Inventors: Adam Juhasz, Costa Mesa, CA (US); Kostadin Vardin, Aliso Viejo, CA (US)

(73) Assignee: Alcon LenSx, Inc., Aliso Viejo, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 219 days.

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(21) Appl. No.: 12/815,179

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(22) Filed: Jun. 14, 2010

(Continued)

(65) Prior Publication Data

US 2011/0304819 A1 Dec. 15, 2011

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(51) Int. Cl.

A61B 3/14 (2006.01)
A61B 3/00 (2006.01)

(52) U.S. Cl. 351/206; 351/208; 351/246

(58) Field of Classification Search 351/205–206,
351/200, 208–210, 221–223, 246

See application file for complete search history.

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Primary Examiner — Dawayne A Pinkney

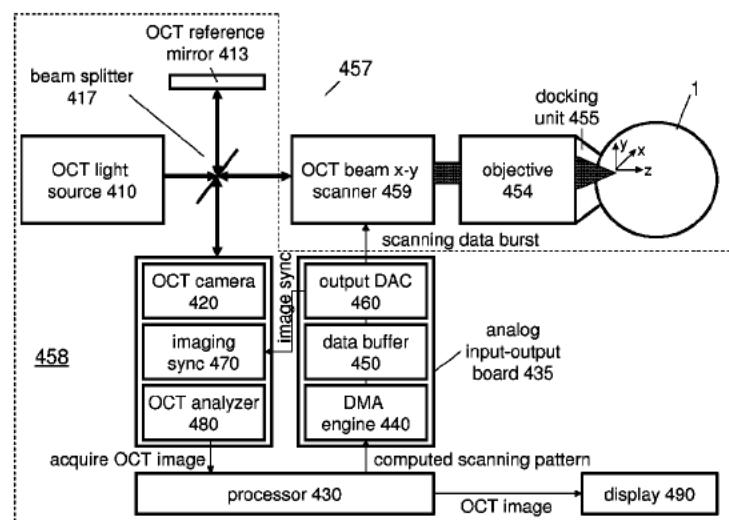
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ABSTRACT

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A docking method for an ophthalmic system may include the steps of aligning a docking unit of the ophthalmic system and an eye; generating an image of an internal structure of the eye by an imaging system; improving an alignment of the docking unit with the internal structure of the eye in relation to the generated image; and docking the docking unit to the eye. The generating the image step may include computing scanning data by a processor corresponding to a scanning pattern; storing the scanning data in a data buffer; transferring the scanning data by the data buffer to an output module; outputting scanning signals by the output module to one or more scanners based on the scanning data; and scanning an imaging beam with the one or more scanners according to the scanning signals.

40 Claims, 12 Drawing Sheets



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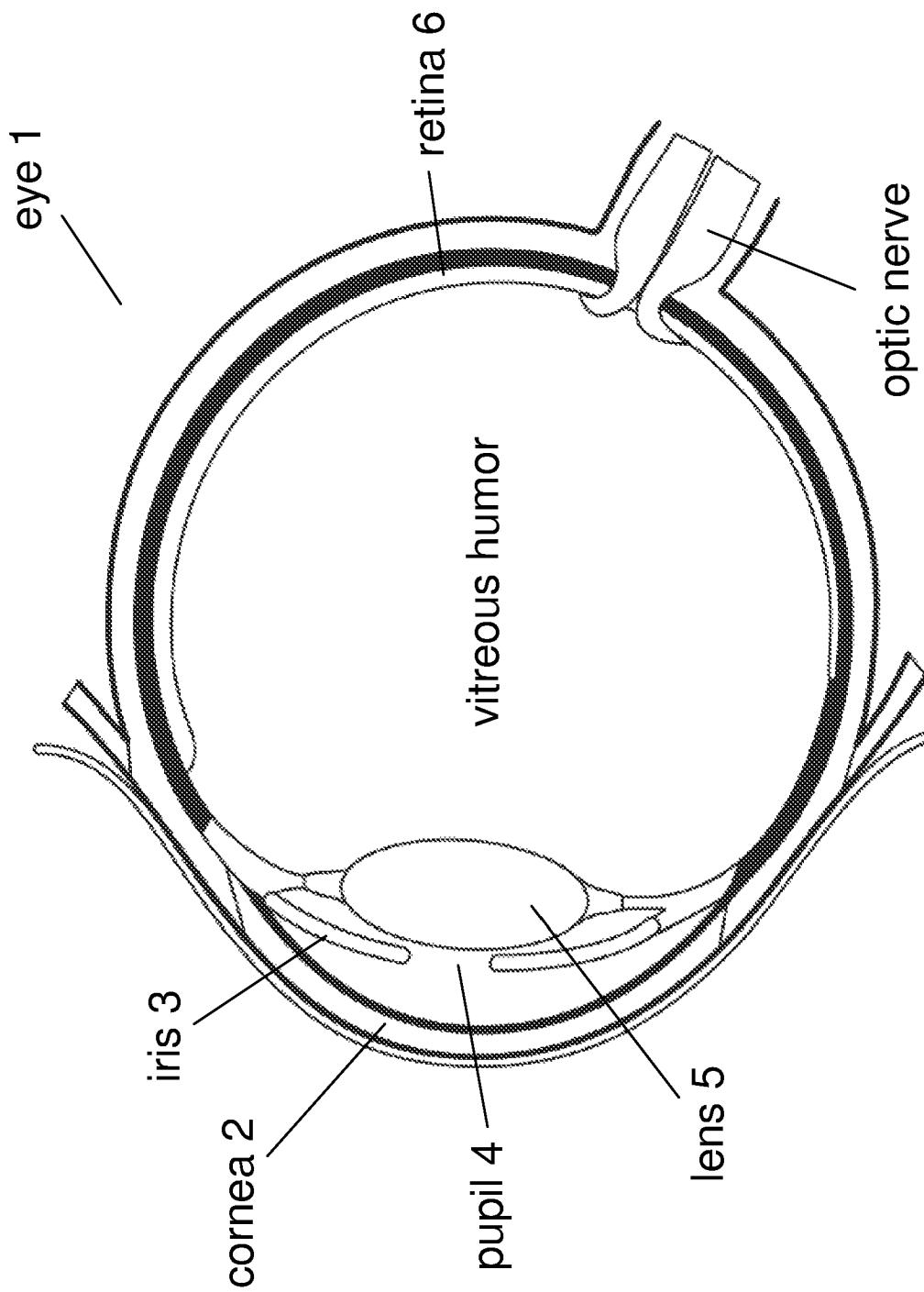


FIG. 1

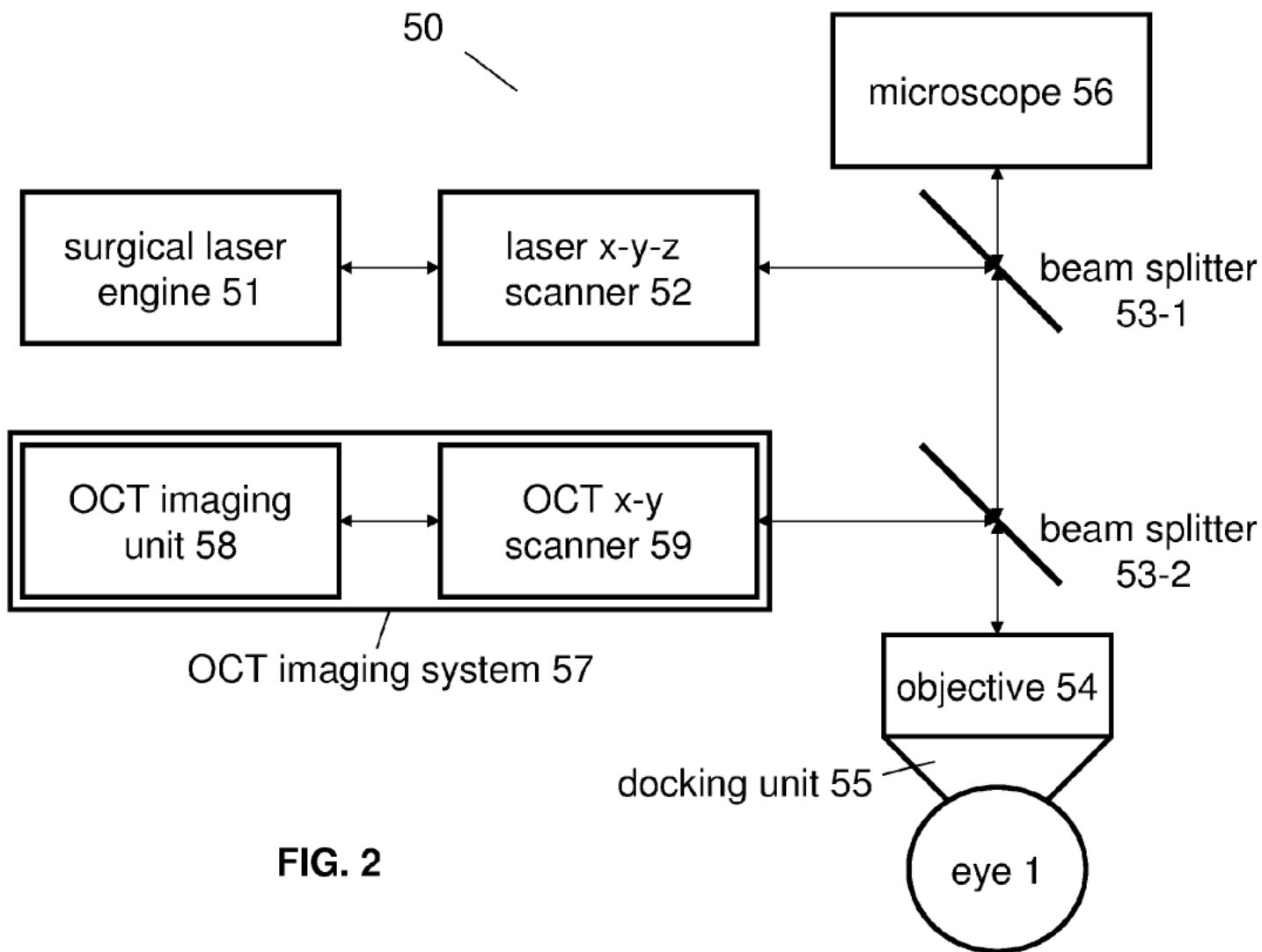


FIG. 2

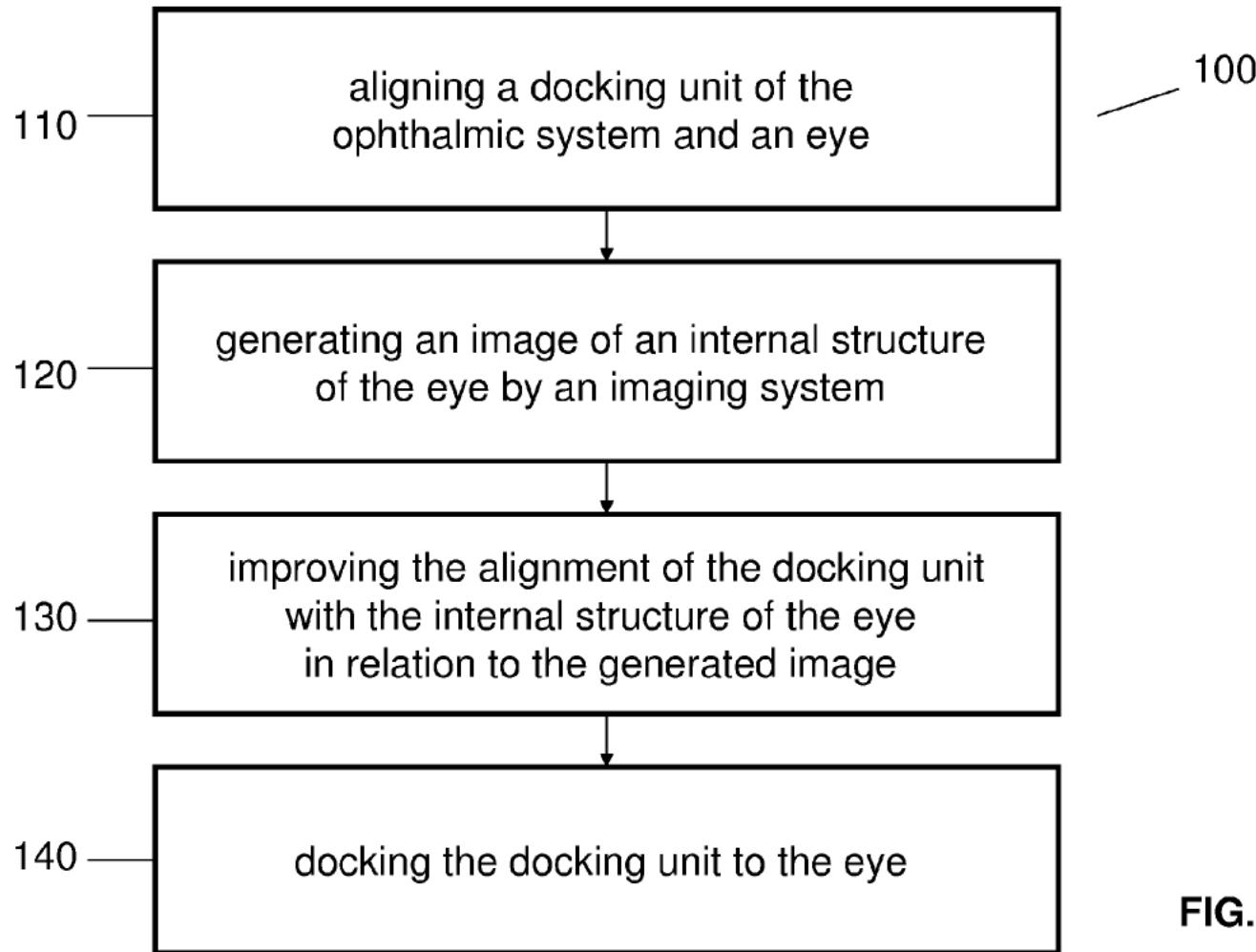


FIG. 3

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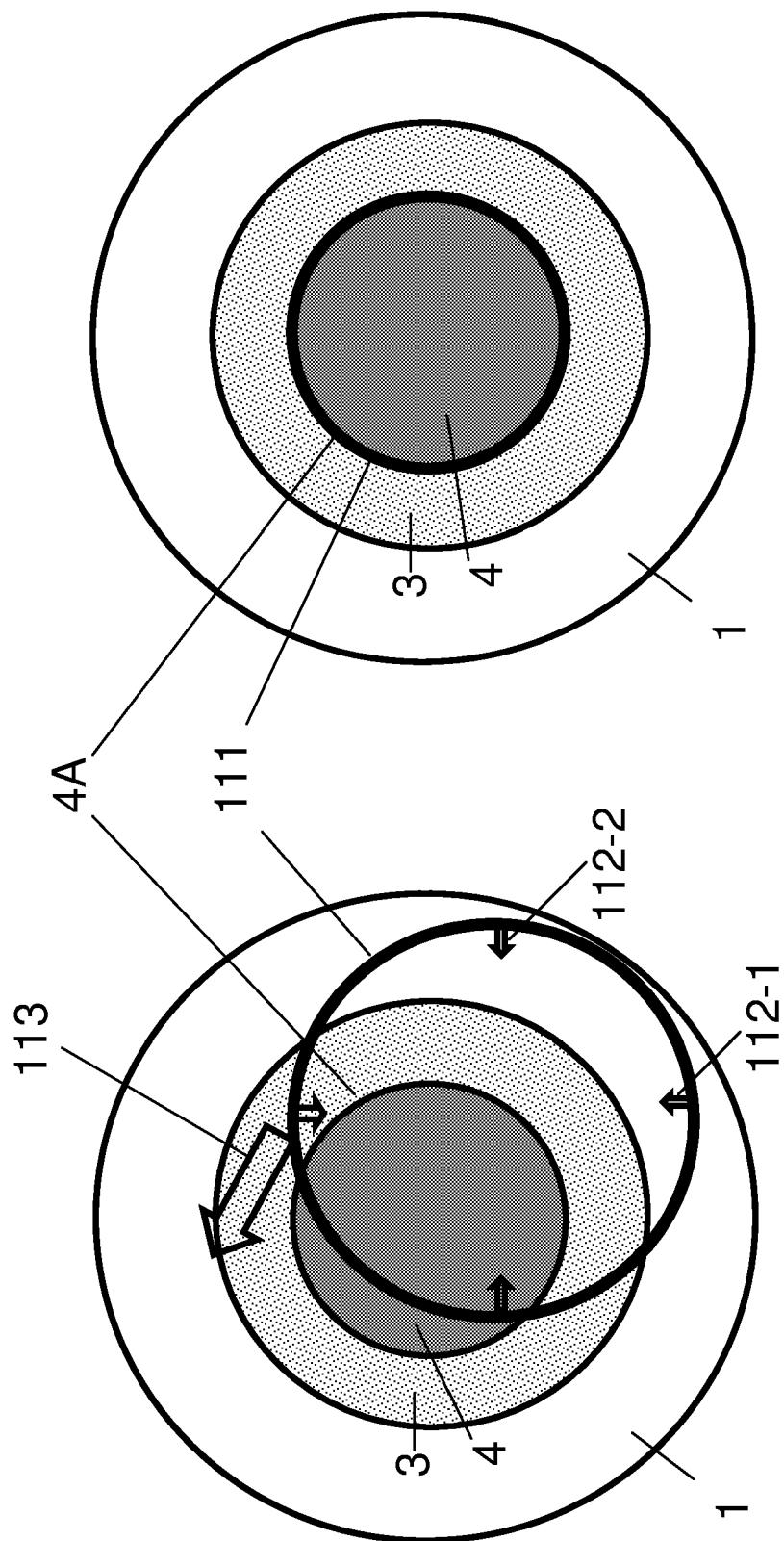


FIG. 4B

FIG. 4A

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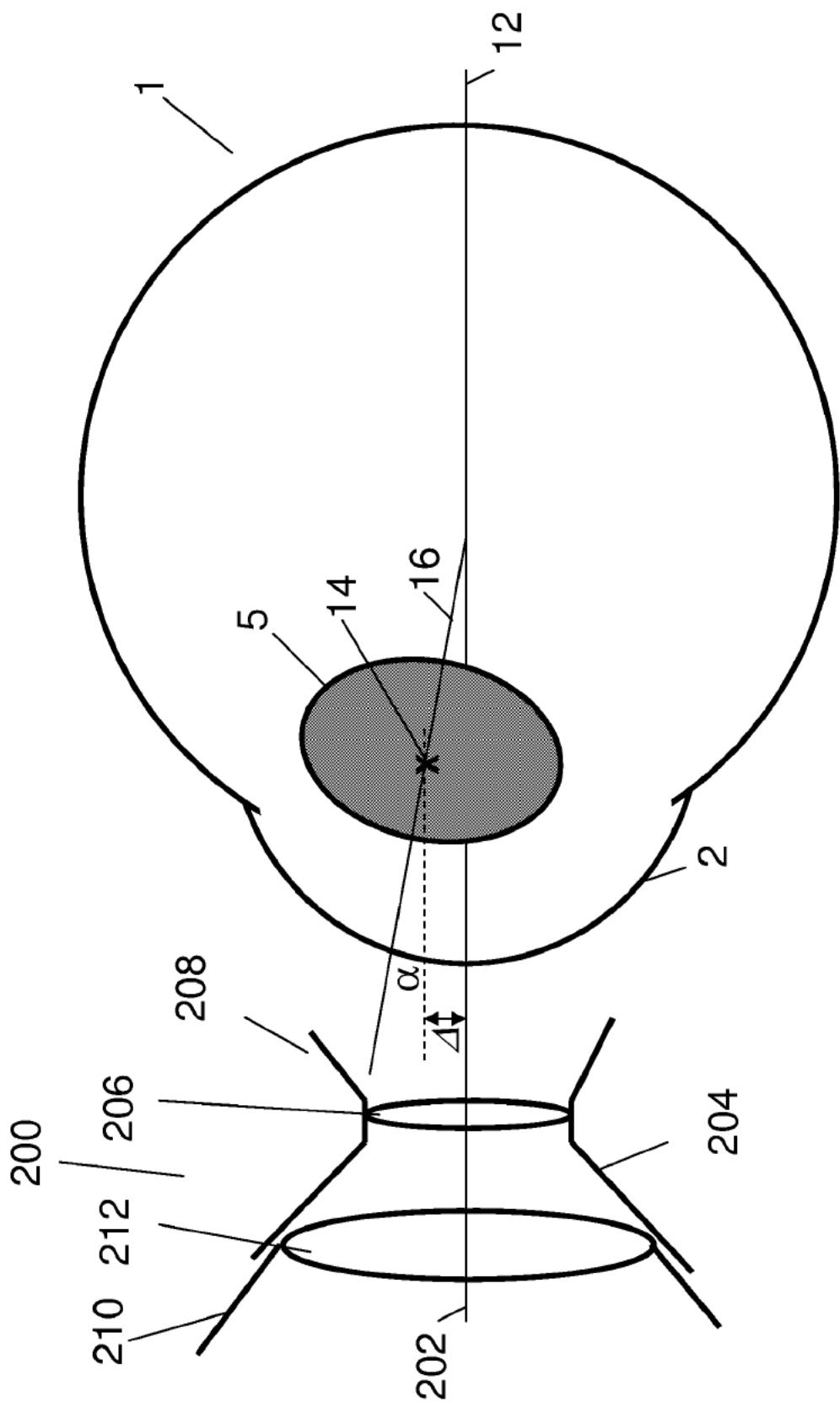


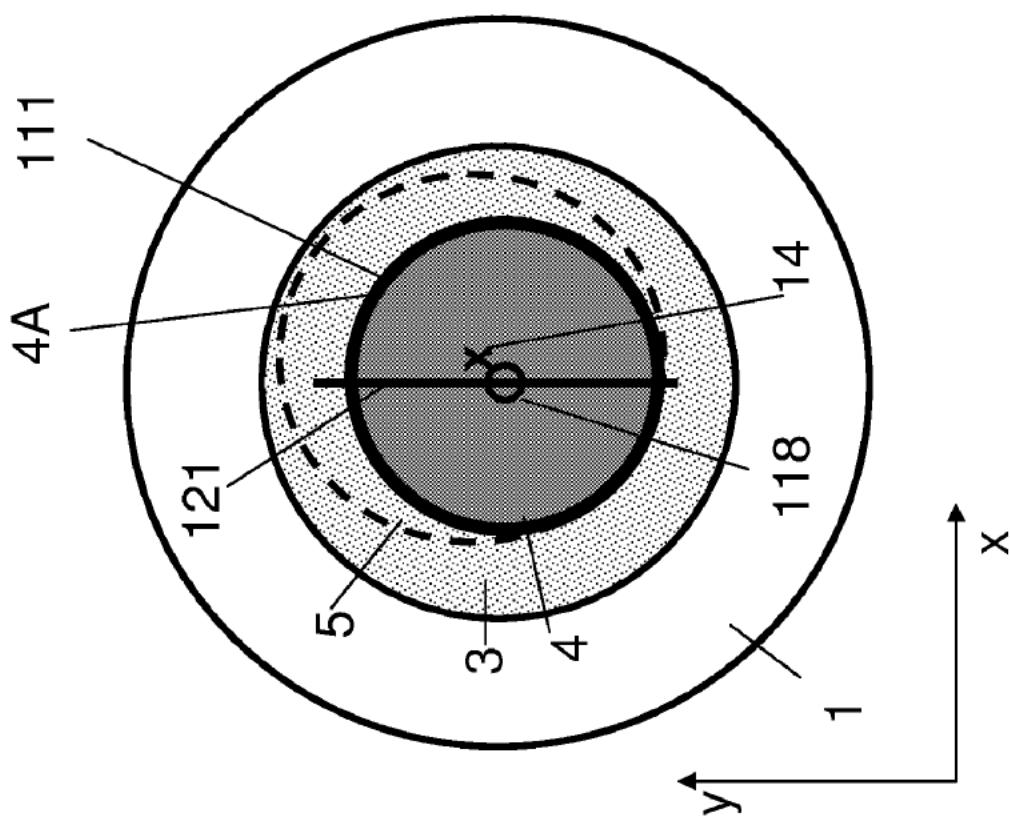
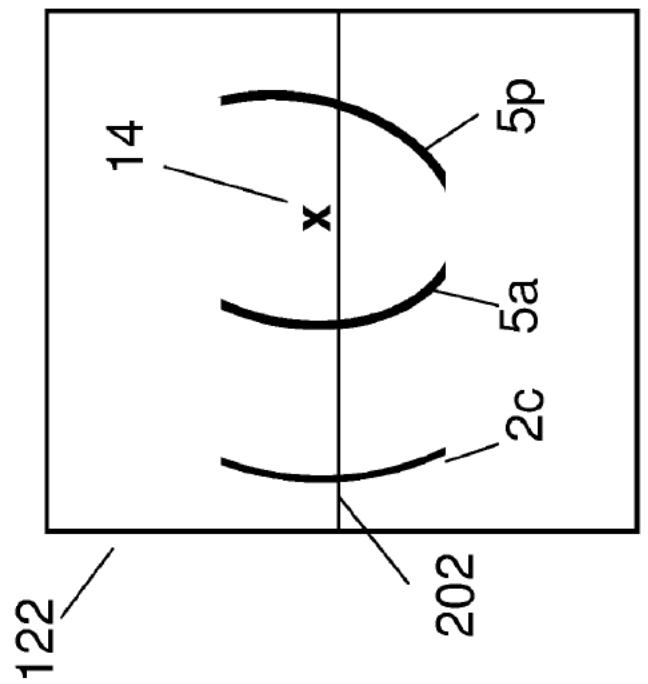
FIG. 5

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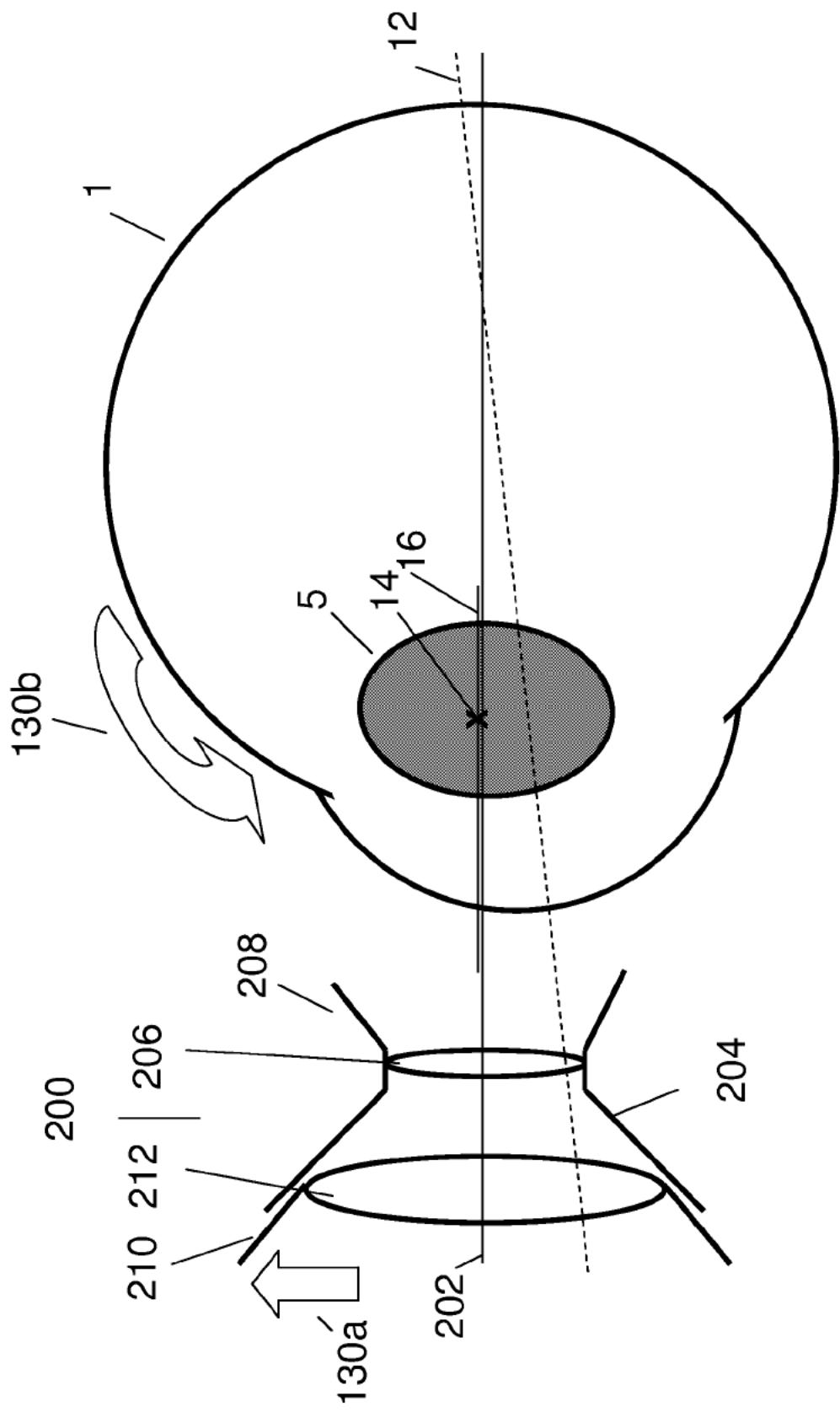


FIG. 7

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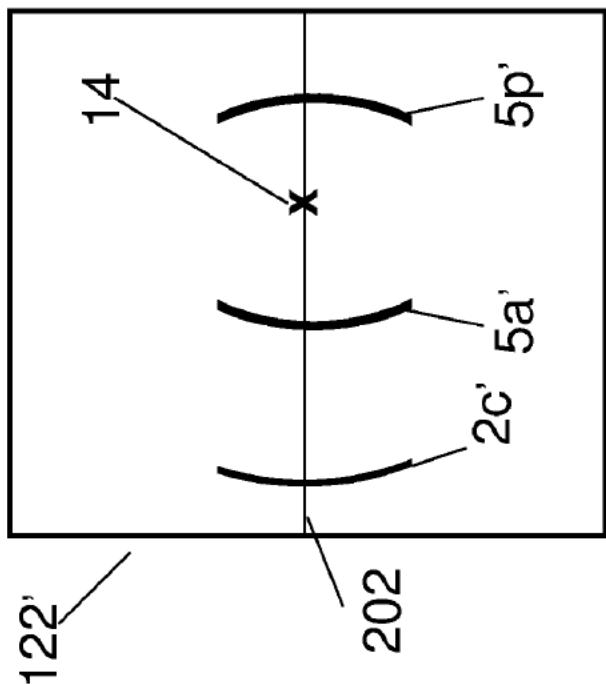


FIG. 8B

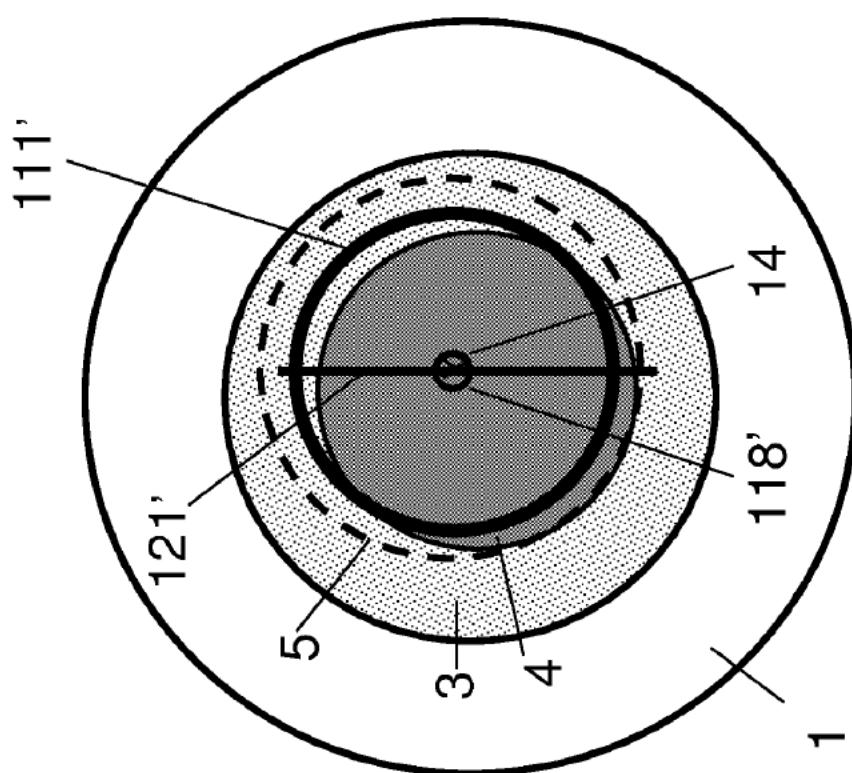


FIG. 8A

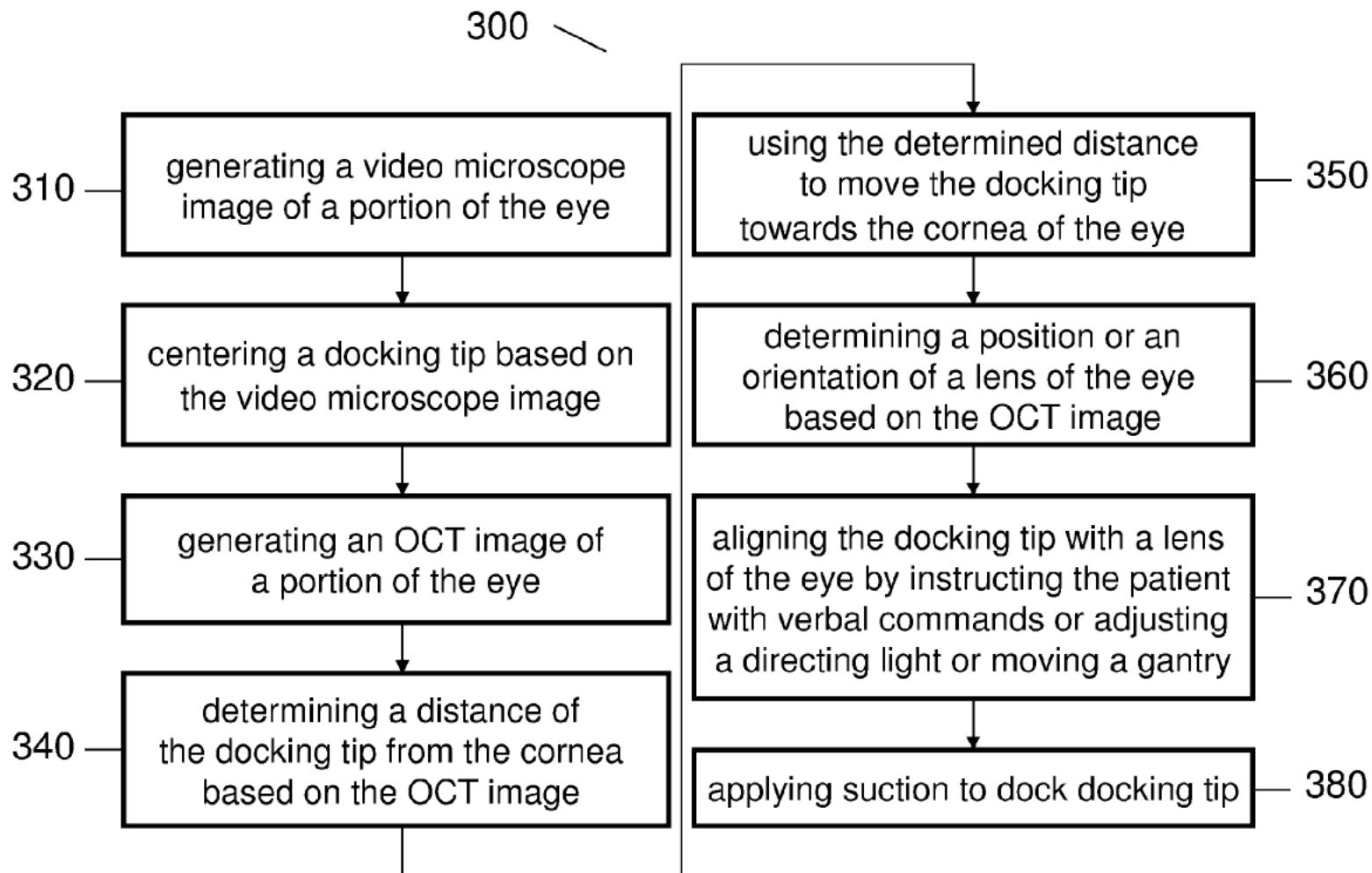


FIG. 9

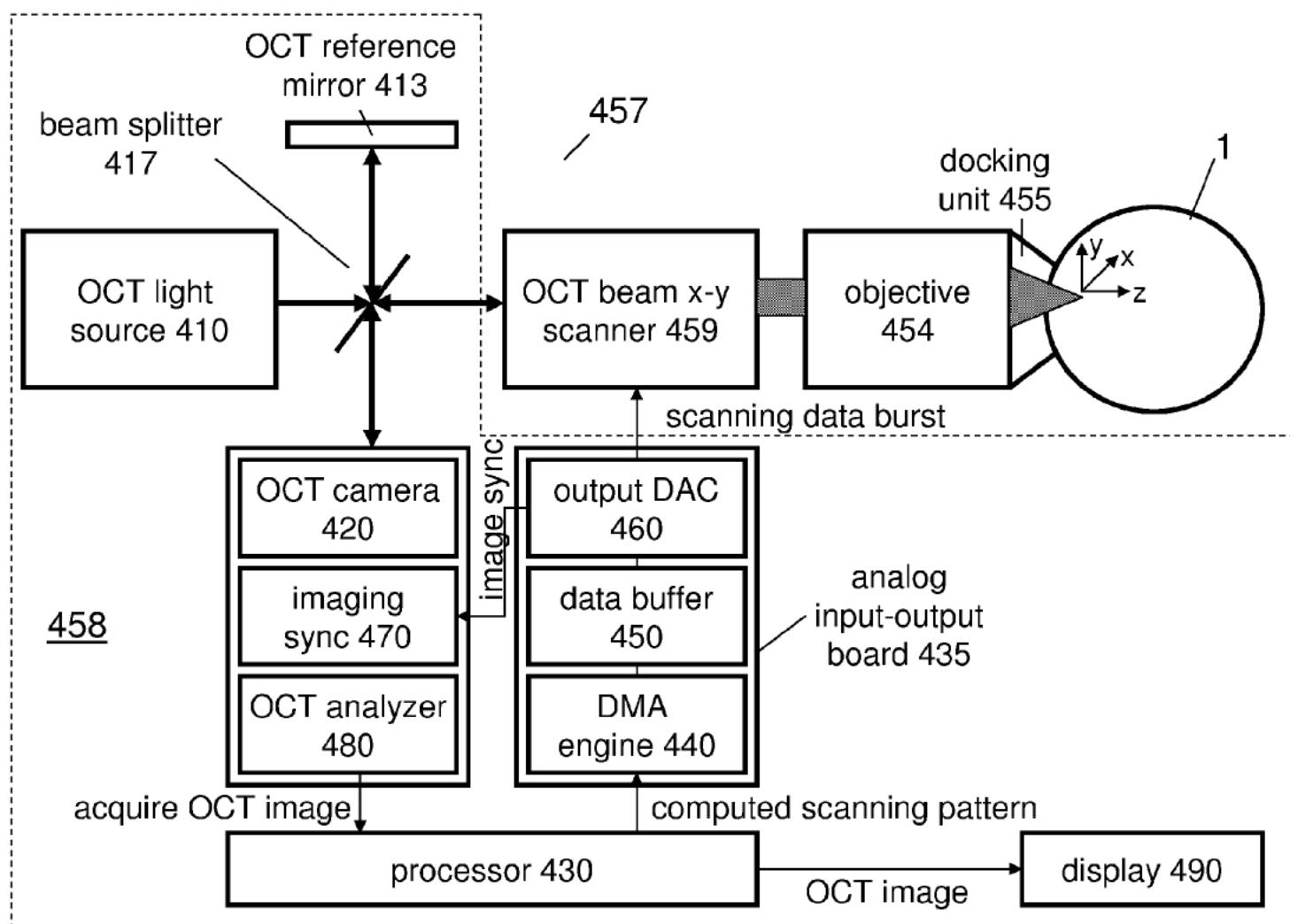


FIG. 10

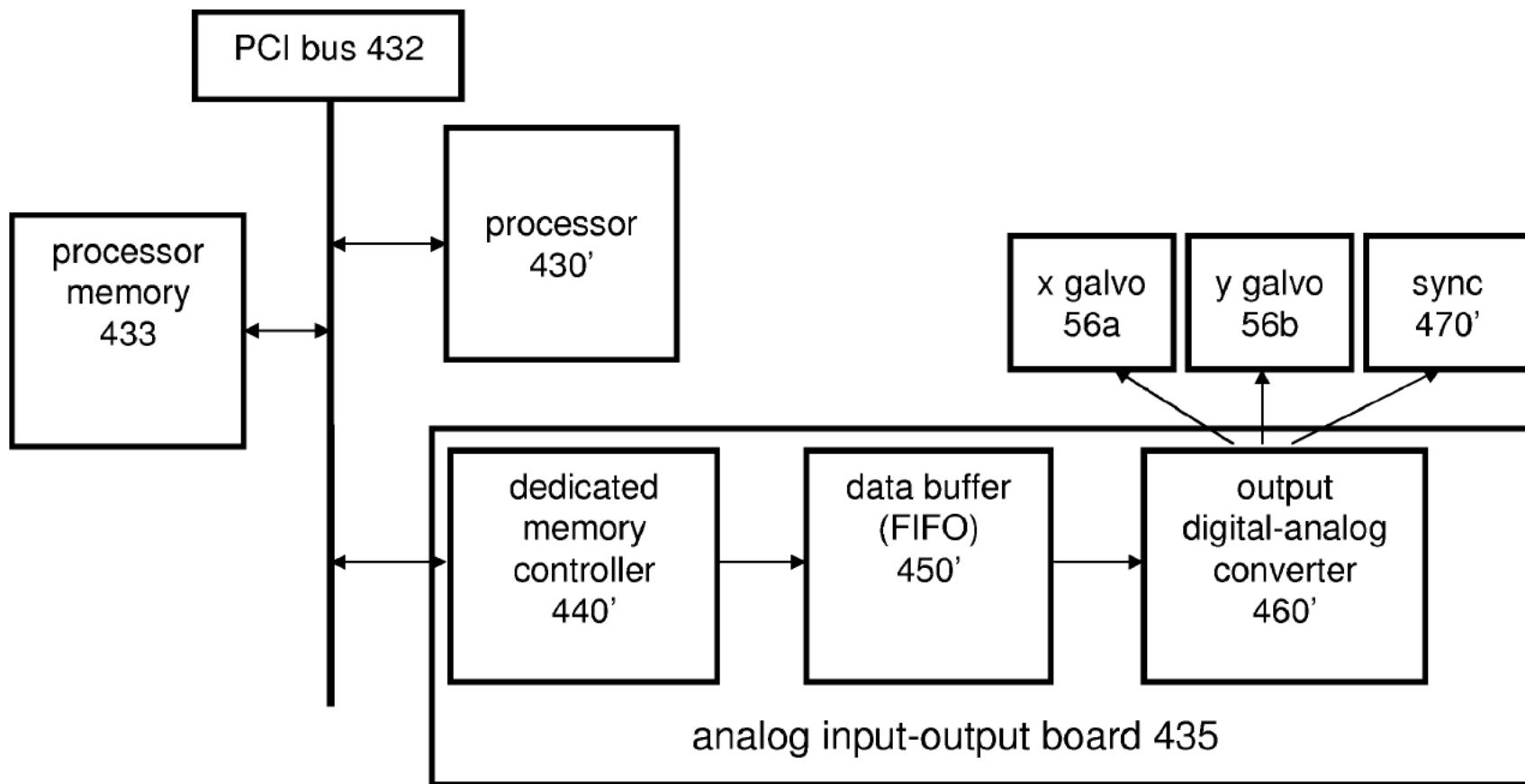


FIG. 11

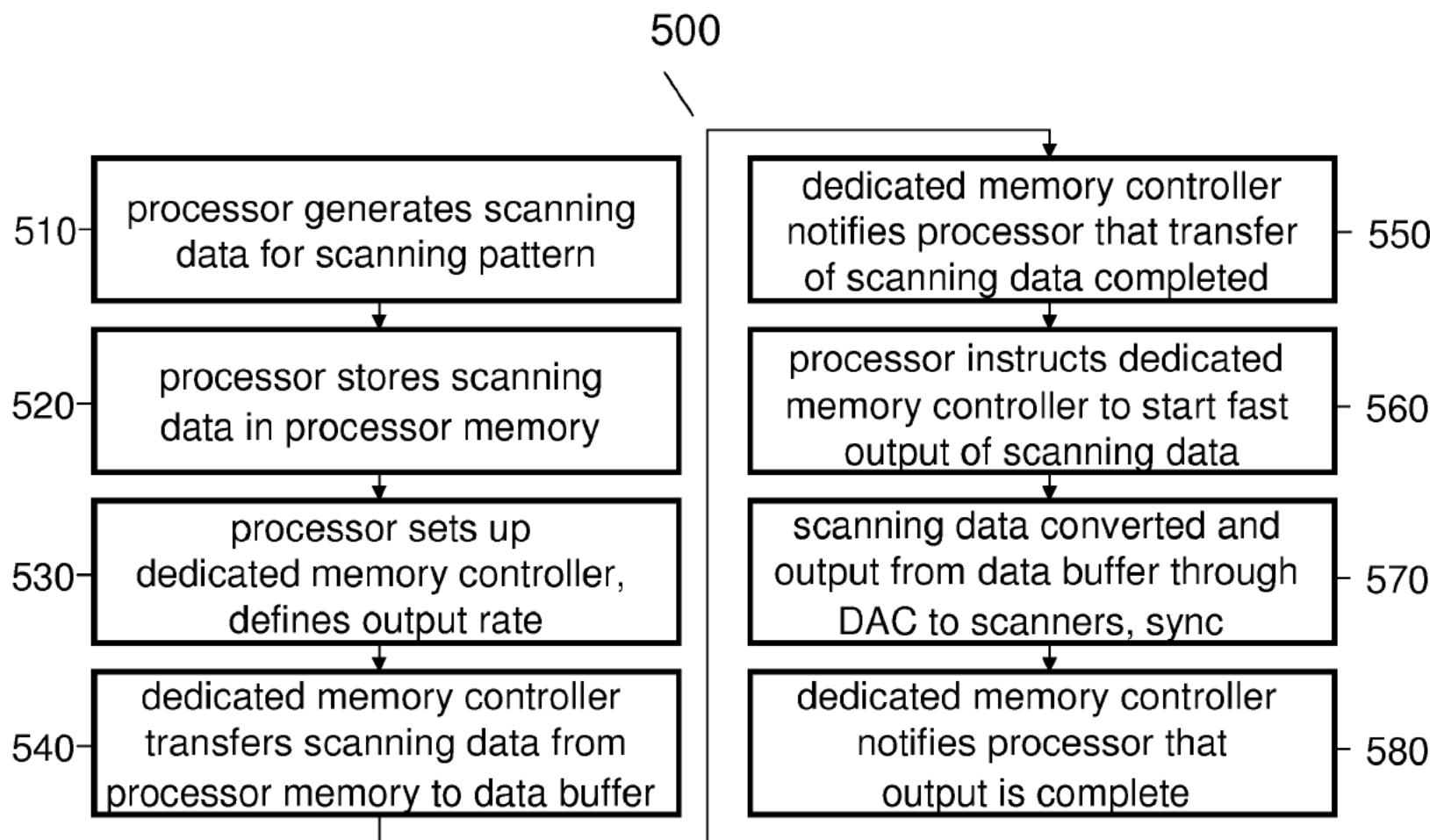


FIG. 12

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**IMAGE-GUIDED DOCKING FOR
OPHTHALMIC SURGICAL SYSTEMS**

TECHNICAL FIELD

This patent document relates to systems and techniques for surgical applications, including ophthalmic surgery. In more detail, the patent document relates to systems and methods for docking ophthalmic surgical systems to a surgical eye with high precision.

BACKGROUND

A variety of advanced surgical laser systems have been developed over the years for ophthalmic surgery, targeting portions of the cornea, the lens, the retina and other structures of the eye. Some of these surgical systems increase the precision of the surgical procedure by creating a well-controlled connection between the ophthalmic surgical apparatus and the ophthalmic target, typically a region or a structure of the eye. In some cases this connection is established by lowering a docking module or unit onto the eye. Certain systems also employ an additional fixation step, such as the application of suction to strengthen the connection. In typical surgical laser systems the precision and control of the ophthalmic surgery is substantially impacted by the precision of these docking and fixation steps and hence improving the precision of the docking procedure can improve the precision of the entire ophthalmic surgical procedure.

SUMMARY

This patent document discloses examples and implementations of systems and techniques for guiding an ophthalmic surgical system to create a well-controlled connection with an ophthalmic target, such as a human eye.

For example, a docking method for an ophthalmic system may include the steps of aligning a docking unit of the ophthalmic system and an eye; generating an image of an internal structure of the eye by an imaging system; improving an alignment of the docking unit with the internal structure of the eye in relation to the generated image; and docking the docking unit to the eye.

The aligning the docking unit step may include using a first imaging system to align a target pattern of the ophthalmic system in relation to a feature of the eye.

The first imaging system can be one of a microscope or a video microscope; the target pattern of the ophthalmic system can include at least one of a center of a contact lens, a center of the docking unit, a docking circle, or a docking cross-hair; and the feature of the eye may be a center of a region of an iris, a pupil, a cornea, a limbus, or a lens; or a circular formation related to a region of the iris, the pupil, the cornea, the limbus or the lens.

The generating an image step may include generating an image with a second imaging system, wherein the second imaging system is one of an optical coherence tomographic imaging system and an imaging system configured to image the internal structure of the eye.

The improving an alignment step may include extracting position information regarding the internal structure of the eye from the generated image; and adjusting a position of at least one of the eye or the docking unit in relation to the extracted position information.

The improving an alignment step may include extracting orientation information regarding the internal structure of the eye from the generated image; and adjusting an orientation of

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at least one of the eye or the docking unit in relation to the extracted orientation information.

The generating the image step may include computing scanning data by a processor corresponding to a scanning pattern; storing the scanning data in a data buffer; transferring the scanning data by the data buffer to an output module; outputting scanning signals by the output module to one or more scanners based on the scanning data; and scanning an imaging beam with the one or more scanners according to the scanning signals.

The computing the scanning data step may include implementing a scanning pattern that includes at least one of a linear pattern, a circular pattern, an oval pattern, a loop pattern, an arc pattern, a raster pattern, an x-y pattern, a crosshair pattern, a star pattern, a spiral pattern, and a pattern with outlying points.

The computing the scanning data step may include inserting synchronizing signals into the scanning data by the processor.

The computing the scanning data step may include computing homing data corresponding to a homing pattern connecting a starting point of the scanning pattern to a previously set point.

The storing the scanning data step may include storing the scanning data in a processor memory; and transferring the stored scanning data from the processor memory to the data buffer partially under the control of a dedicated memory controller.

The dedicated memory controller may include a direct memory access engine; and the data buffer may include a first-in-first-out memory.

The transferring the scanning data step may include outputting the scanning data by the data buffer to the output module in a fast data transfer mode.

The transferring the scanning data step may include outputting the scanning data from the data buffer without sending the scanning data through at least one of a bus connecting the dedicated memory controller and the processor, the processor memory, or the processor.

The transferring the scanning data step may include outputting the scanning data in parallel with the processor performing at least one of processing an image, computing scanning data corresponding to a scanning pattern, or performing a control function.

The transferring the scanning data step may include receiving the scanning data by the output module without an interrupt by another system agent, thereby keeping a jitter of the scanning data below 40 microseconds.

The outputting the scanning signals step may include converting the scanning data into analog scanning signals by the output module, wherein the output module includes a digital-analog converter.

The scanning an imaging beam step may include receiving the outputted scanning signals by a scanning controller and an imaging synchronizer, wherein the scanning signals comprise synchronizing signals; repeatedly adjusting the one or more scanners by the scanning controller according to the scanning signals to scan the imaging beam; and repeatedly synchronizing an imaging camera by the imaging synchronizer according to the synchronizing signals.

The scanning controller may include at least one galvo-controller; and the imaging synchronizer may include at least one ophthalmic coherence imaging camera controller.

In some implementations an integration time of an image recording device can be a limiting factor of an operating speed of an imaging system.

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The outputting the scanning signals step may include outputting the scanning signals at a rate within one of the following ranges: 1 Hz-1 MHz, 100 Hz-1 MHz, or 1 kHz-100 kHz.

The outputting the scanning signals step may include adjusting an output rate of the output of the scanning signals.

The improving the alignment step may include providing a verbal command to a patient to move his eye, moving the patient's head, moving a surgical bed the patient is resting on, moving the patient's eye, moving the docking unit via moving a gantry or an articulated arm, and using a gripper to move the eye, based on the image of the internal structure of the eye.

The improving the alignment step may include adjusting at least one of a fixation beam or a directing light to improve the alignment of the eye and the docking unit; and directing the patient to follow the fixation beam or the directing light with his eye.

The improving the alignment step may include starting the improving the alignment step before the docking unit makes contact with the eye, after the docking unit makes contact with the eye but before an application of a partial vacuum to the docking unit, or after an application of a partial vacuum.

The docking step may include sensing a distance between a reference point of the docking unit and an outer layer of the eye; and lowering the docking unit according to the sensed distance.

In some implementations the reference point can be adjustable.

The docking step may include bringing the docking unit into physical contact with the eye; and applying suction through a portion of the docking unit after the docking unit makes physical contact with the eye.

In some implementations an imaging controller for an ophthalmic system may include a processor that computes scanning data for a scanning pattern; a local memory controller that partially manages a transfer of the computed scanning data from the processor to a data buffer, wherein the data buffer is configured to store the scanning data and to output the scanning data; and an output digital-analog converter, coupled to the data buffer that converts selected scanning data to analog scanning signals and outputs the scanning signals.

The local memory controller may include a direct memory access engine.

The data buffer may include a first-in-first-out memory that outputs the stored scanning data in a fast data transfer mode.

The imaging controller may further include a processor memory; and a bus, coupled to the processor, the local memory controller and the processor memory, wherein the processor is configured to output the computed scanning data to the processor memory through the bus; and the local memory controller is configured to transfer the scanning data from the processor memory to the data buffer through the bus.

In some implementations the data buffer is configured to output the scanning data without sending the scanning data through at least one of the bus, the processor memory, or the processor.

In some implementations the processor is configured to perform at least one of processing an image and computing scanning data, while the data buffer outputs the scanning data.

In some implementations the output digital-analog converter is coupled to the data buffer so that the scanning data, outputted by the data buffer is received without an interrupt by another system agent, thereby keeping a jitter of the scanning data below 40 microseconds.

In some implementations the output digital-analog converter is configured to output the scanning signals to x and y scanning controllers to scan an imaging beam; and synchro-

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nizing signals to an imaging camera to record a returned imaging beam synchronously with the scanning.

In some implementations a method of controlling an ophthalmic imaging may include computing scanning control data by a processor; storing the scanning control data into a data buffer partially under the control of a memory controller; transferring the scanning control data from the data buffer to a signal converter through a dedicated channel; and sending scanning signals to a scanning controller by an output module, wherein the scanning signals are converted from the scanning control data by the signal converter.

The storing the scanning control data step may include storing the computed scanning control data in a processor memory; and moving the scanning control data from the processor memory to the data buffer.

The transferring the scanning control data step may include transferring the scanning data from the data buffer without sending the scanning data through at least one of a bus connecting the local memory controller and the processor, the processor memory, or the processor.

The transferring the scanning control data step may include transferring the scanning data in parallel with the processor performing at least one of processing an image; and computing scanning data corresponding to a scanning pattern.

The transferring the scanning control data step may include transferring the scanning data without an interrupt by another system agent, thereby keeping a jitter of the scanning data below 40 microseconds.

The local memory controller may include a direct memory access engine; and the data buffer may be a first-in-first-out memory.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the human eye.

FIG. 2 illustrates an ophthalmic surgical system.

FIG. 3 illustrates a docking method.

FIGS. 4A-B illustrate an aligning step.

FIG. 5 illustrates the tilt and displacement of a lens relative to the docking unit.

FIGS. 6A-B illustrate a tilted and displaced lens and its image.

FIG. 7 illustrates an improvement of the alignment between the lens and the docking unit.

FIGS. 8A-B illustrate the alignment of the docking unit with the lens after the alignment-improving step, and the corresponding image.

FIG. 9 illustrates a docking method guided by an imaging method.

FIG. 10 illustrates an image-guided docking system.

FIG. 11 illustrates blocks of the image-guided docking system in detail.

FIG. 12 illustrates the steps of a control method of the image-guided docking method.

DETAILED DESCRIPTION

Many ophthalmic surgical systems include a docking unit, or patient interface, that makes contact with a surgical eye and keeps it effectively immobile relative to an objective of the surgical system during an ophthalmic procedure. The precision of the ophthalmic procedure can be increased by increasing the precision of the alignment of the docking unit with the target of the surgery.

In corneal procedures, where the surgical target—the cornea—is unobstructed and visible, aligning the patient inter-

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face with the target can be performed by the surgeon in a relatively straightforward manner.

However, cataract surgeries pose harder challenges for the alignment and docking of the patient interface for several reasons. These challenges include that the targeted lens is located inside the eye and thus it is less visible for, or partially obstructed from the surgeon.

Also, patients often have difficulties aligning their surgical eye with the optical axis of the ophthalmic surgical system even if given guidance and verbal instructions by the surgeon, as e.g. often the patients are given muscle relaxants or are under heavy sedation.

Further, internal eye structures, such as the lens, are often held by their soft support muscles off-center and tilted relative to the visible structures of the eye, such as the pupil. Therefore, even if a surgeon manages to align the pupil with the optical axis of the surgical system, the lens inside the eye may be still displaced and tilted.

Moreover, as the docking unit is lowered to the eye, it exerts pressure on the eye, possibly resulting in additional displacement and tilting of the lens. This problem can be exacerbated even further by applying suction to dock the patient interface.

Implementations and embodiments in this patent document provide docking procedures and systems for increasing the precision of the docking procedure of ophthalmic surgeries by imaging techniques.

FIG. 1 illustrates a human eye 1 in some detail. The eye 1 includes a cornea 2 that receives and refracts the incoming light, an iris 3, a pupil 4 that provides an opening for the light to enter the inner eye and a lens 5 that focuses the light on the retina 6. As stated above, the lens 5 is often not aligned with the pupil 2, and its soft supporting ciliary muscle-system can allow additional displacement and tilt when the eye 1 is pressured by the docking unit, exacerbating the problem of misalignment with the docking unit.

Implementations and embodiments in this patent document provide docking procedures and systems for increasing the precision of the docking procedure of ophthalmic surgeries by imaging techniques.

FIG. 2 illustrates an ophthalmic laser surgical system 50. The surgical system 50 can include a surgical laser engine 51 that generates the surgical laser beam. The surgical laser beam can be scanned across the surgical target region by a laser x-y-z scanner 52. The surgical laser beam can be coupled into the main system optical path by a beam splitter 53-1, redirecting it to an objective 54. The objective 54 can be part of or may contain a delivery tip, distal end, or lens cone.

In some implementations, parts of the laser x-y-z scanner 52, such as a z scanner block, can be located after the beam splitter 53-1 in the optical path. The z scanner block can be a separate unit, or may include more than one block, or can be part of the objective 54. Each of the x, y, and z scanners may contain more than one functional unit. For example, multiple minors can be used to perform the scanning in the x direction or the y direction, or multiple and separate lens groups can be used for an optimized z scanning.

A docking unit 55 can be removably appended to the objective 54 to make contact with the eye 1 to increase the precision of the targeting of the surgical laser beam into the surgical target region in the eye. The docking unit may be integrated into one piece or may contain more than one piece. A first part of a multi-piece docking unit can be first attached to the surgical eye, whereas a second part of the docking unit can be first attached to the objective 54, or a delivery tip. Subsequently, the first and second parts of the docking unit can be locked together. The docking unit 55 may be referred to as a patient interface, application tip, docking tip, lens cone, or

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applanation device, and may contain a contact lens or applanation lens which may make a contact with the eye or can be disposed close to the eye.

The surgical and docking procedures can be assisted by various imaging systems. In some surgical systems 50, a first imaging system, such as an ophthalmic surgical stereo microscope or video microscope 56, can be provided to image the surgical target region for the surgeon. The (ophthalmic or video) microscope 56 may make use of an observational or

10 imaging light.

The imaging light may share part of the main optical path of the surgical system 50, or can be projected directly to the target region. In a shared-path implementation, the observational light can be generated close to the microscope 56, subsequently guided to the eye and returned from the eye, entering the main optical path or optical train of the surgical system 50 through the beam splitter 53-1. In a non-shared-path implementation, the imaging light can be generated close to and outside the objective 54 and directly projected onto portions of the eye. In this embodiment only the returned portion of the imaging light may be guided through the main optical pathway of the system to the microscope 56.

Some implementations may include a second imaging system in the surgical system 50 to provide imaging data about the inner structures of the eye and the target region. Using the images from the first and second imaging systems in synergy can provide enhanced guidance for the ophthalmic procedure in general and improve the accuracy of the docking of the patient interface in particular.

30 In some surgical systems 50 the second imaging system can be an optical coherence tomography (OCT) imaging system 57. The OCT imaging system 57 can be a time-domain, a swept-source or a spectrometer based OCT imaging system, among others. The OCT imaging system 57 can include an OCT imaging unit 58 that creates an OCT imaging beam, guides the OCT imaging beam toward the eye and processes the OCT imaging beam returned from the eye. The OCT imaging system 57 can also include an OCT x-y scanner 59 that scans the OCT imaging beam across the target region in the x-y plane which can be e.g. perpendicular to the optical axis.

40 In general, the notation “x-y-z” is used in a broad sense throughout this document: it can refer to scanning in three directions which make substantial angles with each other. 45 These angles, however, may not be necessarily right angles. Also, the scanning may be performed along either straight or curved lines, on flat or curved surfaces in a grid, raster, concentric, spiral, or any other pattern. In some implementations the OCT imaging beam may be scanned by the surgical laser x-y-z scanner 52. In others, only some of the scanning functionalities of the surgical laser beam and the OCT imaging beam are performed by a shared scanner block, such as the x-y scanning functionality. Some OCT systems, such as time domain OCT systems require a z scanning of the beam, whereas others, such as spectrometer based OCT systems, do not require z scanning as they capture image data from all depth at essentially the same time.

50 The OCT imaging beam can be coupled into the main optical path of the surgical system 50 through a beam splitter 53-2, and directed into the target region by the objective 54 and docking unit 55. In some implementations, part or all of the z scanning functionality can be performed by a z scanner disposed in the shared optical path, after the beam splitter 53-2. The z scanner can be even part of the objective 54.

60 FIG. 3 illustrates a docking method 100 for the ophthalmic laser surgical system 50, where the docking method 100 may include:

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An aligning step 110 for aligning the docking unit 55 of the ophthalmic system 50 and the eye;

An imaging step 120 for generating an image of an internal structure of the eye by an imaging system;

An alignment-improving step 130 for improving the alignment of the docking unit 55 with the internal structure of the eye in relation to the generated image; and

A docking step 140 for docking the docking unit 55 to the eye.

These steps are described in detail below.

The aligning step 110 may include using the first imaging system to align a target pattern of the ophthalmic laser surgical system 50 with a feature of the eye. This aligning step 110 can be performed e.g. in relation to lowering the docking unit 55 towards the eye. The first imaging system may be the ophthalmic surgical microscope or video microscope 56.

The target pattern of the ophthalmic laser surgical system 50 can include at least one of a mark of a center of a contact lens, of a center of the docking unit 55, or of an optical axis of the objective 54, the docking unit 55 or the contact lens. In other implementations, it can include a docking circle, a docking cross-hair, or any other docking target pattern, as well as a combination of the above patterns. This target pattern can be formed in the optics of an ophthalmic surgical microscope 56, or can be electronically generated and displayed on a display or screen of a video microscope 56.

The feature of the eye can be a center of a region of the cornea 2, the iris 3, the pupil 4, a limbus, a sclera, or the lens 5; or a circular formation related to a region of the cornea 2, the iris 3, the pupil 4, the limbus, the sclera, or the lens 5.

FIGS. 4A-B show an illustrative example of the aligning step 110. In FIG. 4A, the video microscope 56 displays the eye 1 as seen through the objective 54 of the laser surgical system 50, and a variable radius target pattern circle 111, centered at the shared optical axis of the objective 54 and docking unit 55. As the surgeon lowers the docking unit 55 towards the eye, in a pattern adjusting step 112 he may adjust the variable radius of the target pattern circle 111 to be essentially equal to the radius of the inner circular edge 4A of the patient's pupil 4, as indicated by the arrows 112-1 and 112-2. In addition, in a pattern moving step 113, the surgeon may also adjust or move the docking unit 55 in the x-y plane, as shown by the arrow 113, to align the target pattern circle 111 with the inner circular edge 4A of the pupil 4 before, during or after the radius adjustment.

The radius of the target pattern circle 111 can be chosen to be somewhat different from the radius of the inner circular edge 4A of the pupil 4 as long as the radius enables the surgeon to align the target pattern circle 111 with the pupil 4 with a desired precision. In other embodiments, any other target pattern can be used, including arcs, cross-hairs, and raster patterns, as listed above.

FIG. 4B illustrates that the adjusting of the variable radius of the target pattern circle 111 in step 112 and the moving of the docking unit 55 in the x-y plane in step 113 may be repeatedly and iteratively performed until the target pattern circle 111 essentially coincides with the inner circular edge 4A of the pupil 4. Doing so aligns the shared optical axis of the objective 54 and the docking unit 55 with the axis or center of the pupil 4.

During this aligning step 110 the docking unit 55 may get lowered toward the eye, possibly even getting into physical contact with the eye during an adjustment of the z directional position of the docking unit 55. However, in either case the docking unit 55 still can remain movable relative to the eye, allowing the surgeon to carry out the aligning step 110, possibly iteratively. Even at the end of aligning step 110 the

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docking unit may remain movably connected to the eye to allow for a possible subsequent aligning step.

In some implementations, the aligning step 110 may not involve a target pattern. In these cases the alignment of the docking unit 55 may be guided primarily by the visual assessment of the surgeon.

Embodiments of this aligning step 110 align the docking unit 55 and the eye to a certain precision. If the docking unit is docked to the eye after aligning step 110, an ophthalmic procedure can be performed with a certain precision. For some procedures this precision may be sufficient, but others may benefit from a higher precision.

FIG. 5 illustrates such a situation. Even after an optical axis 202 of a docking unit 200 is aligned with the pupil 4 of the eye in the aligning step 110, the lens 5 of the eye may remain displaced and tilted relative to the optical axis 202, as the lens 5 may not be aligned with the pupil 4 for one of the reasons outlined above. Here, the docking unit 200 can be an embodiment of the docking unit 55.

In FIG. 5, even after an optical axis 12 of the pupil 4 and the eye has been aligned with the optical axis 202 of the docking unit 200 in the aligning step 110, a center 14 of the lens 5 is still offset by Δ from the shared optical axis 12/202 of the pupil 4 and the docking unit 200, and a symmetry axis 16 of the lens 5 still makes an angle α with the shared optical axis 12/202.

Here, the body or housing 204 of the docking unit 200, sometimes called patient interface, lens cone, or application tip, may contain a contact lens, applanation lens or applanation plate 206 and a skirt or flexible seal 208, which makes contact with the outer eye-surface, typically with the cornea, limbus, or sclera. The docking unit 200 can be affixed to an embodiment of the objective, delivery tip, or distal end 210 or 54, which may include several lenses, the ultimate lens being distal lens 212.

FIGS. 6A-B illustrate the imaging step 120 in some detail.

FIG. 6A illustrates that in the aligning step 110 the docking unit 55 or 200 can be properly aligned and centered with the pupil 4 using the video microscope 56, as evidenced by the target pattern circle 111 overlapping with the inner circular edge 4A of the pupil 4, and its center 118 (denoted by a circle) being at the center of the pupil 4. However, the lens 5, shown with a dotted line as its outer perimeter is hidden from the view of the video microscope 56, can be off-center with respect to the pupil 4. This is indicated also by the center 14 of the lens, denoted by an x, being off the center 118 of the target pattern 111, denoted by the circle. Furthermore, the axis 16 of the lens 5 can be tilted relative to the shared axis 202/12 of the docking unit 200 and pupil 4.

Therefore, even after the aligning step 110, the target pattern circle 111 may not be well-aligned with the lens 5, and thus the precision of cataract procedures centered with the target pattern circle 111 may not be optimal. This non-optimal precision can be improved by performing the imaging step 120.

FIGS. 6A and B illustrate that in a typical case, the imaging step 120 can include a linear scan 121 across the center 118 of the target pattern circle 111 which coincides with the center of the pupil 4. This linear scan 121 generates a y-z image 122 that includes an image 2c of a corneal segment and images 5a and 5p of segments of the anterior and posterior lens capsule, respectively. The images of the lens segments 5a and 5p appear tilted and off center relative to the optical axis 202 in the y-z image 122, even if the corneal segment image 2c appears centered, since the lens 5 can be tilted and off-center relative to the cornea and pupil. Therefore, providing the

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images of the lens segments **5a** and **5p** may help the surgeon to improve the alignment of the docking unit **200** with the tilted and off-center lens **5**.

In other implementations, the imaging step **120** can involve generating an image with a line scan along a linear pattern, an arc, a crosshair pattern, a star pattern, a circular pattern, an oval pattern, a loop pattern, a spiral pattern, a concentric multi-circle pattern, a shifted multi-circle pattern, a line pattern, and with a two dimensional scan along an x-y, raster or grid scanning pattern and a pattern with outlying points.

The imaging step **120** can involve generating an image with an embodiment of the optical coherence tomographic (OCT) imaging system **57**, as described in detail above and below. The imaging step **120** can be also performed with another imaging system, capable of imaging an internal structure of the eye.

FIG. 7 illustrates that the alignment of the docking unit **200** with the lens **5** can be improved by the alignment-improving step **130**, based on the imaging step **120**.

In one aspect, the alignment-improving step **130** can include extracting position information regarding the lens **5** from the generated image **122**, and adjusting a position of at least one of the eye **1** or the docking unit **200** in relation to the extracted position information. In some implementations, other internal eye-structures can be targeted, such as the nucleus of the lens, or a retinal structure.

In an implementation, the surgeon can analyze the y-z image **122**, generated by the imaging step **120**, and determine the offset Δ of the lens center **14** from the optical axis **202** of the docking unit **200**. Based on this determination, the surgeon can shift either the eye, or the docking unit, or both, to overcome this Δ offset, as indicated by arrow **130a**. This adjustment-improving step **130** can reduce or even eliminate the offset Δ between the lens center **14** and the optical axis **202**. Typically, this shift **130a** can offset the optical axis **202** of the docking unit **200** from the optical axis **12** of the lens **5**.

The shift **130a** may be performed iteratively because in the first try the surgeon may not have determined the offset Δ precisely. To remedy this, in some implementations the alignment-improving step **130** may be followed by a repeated imaging step **120'** to determine how the offset Δ was changed by the shift **130a**. This repeated imaging step **120'** can be followed by a repeated alignment-improving step **130'** based on the updated image **122'** generated by the repeated imaging step **120'**, and so on. In efficient implementations, the offset Δ is reduced step-by-step. In other implementations, even if Δ increases during a step, subsequent steps reduce it eventually.

The shift **130a** can be performed by giving a verbal command to the patient to move his/her eye, or by physically moving the patient's head, or the surgical bed the patient is resting on, or by manually moving the patient's eye, or by moving a fixation light of a fixation light source, or by moving a directing light on a directing light display, in either case directing the patient to follow the light with his eye, or by moving the docking unit **200** in an x-y plane via moving a gantry or an articulated arm. In implementations using two piece docking units, the piece which was attached to the eye, such as a gripper, can be used to move or rotate the eye. The fixation or directing light can be directed either into the surgical eye or into the non-surgical eye. These adjustments can be performed manually by the surgeon, or by operating one or more electric actuators, or by a computer. In some cases, more than one of the above types of shifts can be performed jointly.

FIG. 7 also illustrates that in other implementations the alignment-improving step **130** may include extracting orientation information regarding the lens **5** or another targeted

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internal structure of the eye from the generated image **122**, and adjusting an orientation of at least one of the eye **1** or the docking unit **200** in relation to the extracted orientation information.

In an implementation, the surgeon can analyze the y-z image **122**, generated by the imaging step **120**, and determine the angle α between the optical axis **16** of the lens **5** and the optical axis **202** of the docking unit **200**. Based on this determination, the surgeon can rotate either the eye, or the docking unit, or shift the docking unit, or adjust an optical path of the laser beam in the laser surgical system **50** to overcome this a misalignment. The option of rotating the eye is indicated by arrow **130b**. This alignment-improving step **130** can reduce or even eliminate the angle α between the optical axis **16** of the lens **5** and the optical axis **202** of the docking unit **200**. This alignment-improvement is typically achieved by introducing an angle between the optical axis **12** of the eye and the optical axis **202** of the docking unit **200**, as indicated by the dotted line.

The rotation **130b** may be performed iteratively because in the first try the surgeon may not have determined the angle α precisely. To remedy this, in some implementations the alignment-improving step **130** may be followed by a repeated imaging step **120'** to determine the angle α' after the rotation **130b** from a repeated image **122'**, followed by a repeated alignment-improving step **130'** based on the image **122'** generated by the repeated imaging step **120'** and so on. In efficient implementations, the angle α is reduced step-by-step. In other implementations, even if α increases during a step, subsequent steps eventually reduce it.

The rotating step **130b** can be performed by giving a verbal command to the patient to rotate his/her eye, or by manually rotating the patient's head, or by physically rotating the patient's eye, or by moving a fixation light of a fixation light source, or a directing light displayed on a display, in either case directing the patient to follow the light with his eye, or by moving or rotating the docking unit **200** in the x-y plane via moving a gantry or an articulated arm. The fixation or directing light can be directed either into the surgical eye or into the non-surgical eye. In implementations using two piece docking units, the piece which was attached to the eye, such as a gripper, can be used to move or rotate the eye. These adjustments can be performed manually by the surgeon, or by operating one or more electric actuators, or by a computer. In some case, more than one of the above types of shifts can be performed jointly.

FIGS. 8A-B illustrate an outcome of the imaging step **120** and alignment-improving step **130**.

FIG. 8A illustrates that after a successful alignment-improving step **130**, a shifted target pattern circle **111'** may have become concentric with the lens **5** instead of the pupil **4**. Correspondingly, the shifted linear scanning line **121'**, across the shifted center **118'** of the target pattern circle **111'**, can now go through the center **14** of the lens **5** instead of the center of the pupil **4**.

Some implementations may display both the first target pattern circle **111** concentric with the pupil **4**, as well as a second target pattern **111'** which is shifted by the alignment-improving step **130** to be concentric with the lens **5**.

FIG. 8B illustrates that after an efficient alignment-improving step **130**, a repeated imaging step **120'** may record a cross-sectional y-z image **122'** showing that the center **14** of the lens now lies on the optical axis **202** of the docking unit **200**. Further, the images of the anterior and posterior capsule segments **5a'** and **5p'** after the relative rotation and shift of the eye and the docking unit **200**, are close to symmetric, indi-

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cating that the optical axis 16 of the lens is approximately aligned with the optical axis 202 of the docking unit 200.

Achieving alignment of the docking unit 55/200 with the hard-to-see, displaced and tilted lens 5 instead of the visible pupil 4 with such an improved precision is one of the benefits of the image-guided docking method 100.

FIG. 9 illustrates that an implementation of a related image-guided docking method 300 may include the steps of:

A video imaging step 310, for generating a video microscope image of a portion of the eye;

A centering step 320, for centering a docking tip based on the video microscope image;

An OCT imaging step 330 for generating an OCT image of a portion of the eye;

A distancing step 340 for determining a distance of the docking tip from the cornea based on the OCT image;

A moving step 350 for using the determined distance to move the docking tip towards the cornea of the eye;

A determining step 360 for determining a position or an orientation of a lens of the eye based on the OCT image;

An aligning step 370 for aligning the docking tip with a lens of the eye by instructing the patient with verbal commands, or adjusting a directing light or moving a gantry; and

A docking step 380 for applying suction to dock the docking tip.

Several of the steps 310-380 of the method 300 can proceed analogously with the corresponding steps 110-140 of the method 100. In addition, the distance-determining step 340 can include determining the distance between the cornea 2 of the eye and the docking tip, which can be the docking unit 55 or 200, or any other patient interface. In this step 340, the distance from the docking tip can be based on a reference point. This reference point can be located in the optical system of the surgical laser system 50, for example in the objective 54. This reference point can be movable, and may be adjusted or offset based on various considerations.

FIG. 10 illustrates an OCT imaging system 457 to illustrate the details of the imaging step in greater detail. The OCT imaging system 457 can include an OCT imaging unit 458 and an OCT x-y scanner 459.

The principles of the operation of OCT imaging systems are well known and documented. The OCT system 457 can be a (a) time domain, a (b) swept source or a (c) spectrometer based OCT. The (a) and (b) types of OCT imaging systems use a narrow band OCT light source 410 and scan the beam's focal point in the z-direction, thus they provide imaging information corresponding to different z-depths sequentially in time. The (a) type time domain OCT systems move a reference mirror, whereas the (b) type swept source OCT systems sweep the wavelength of the laser beam.

The (c) type spectrometer based OCT systems utilize a broad band OCT imaging light source 410 and capture images from a range of z-depths essentially simultaneously, or in parallel, corresponding to the different wavelengths within the broad band of an OCT imaging light source. Because of this parallel imaging aspect, spectrometer-based OCT systems can be substantially faster than sequential OCT systems. The (b) and (c) type OCT systems are sometimes referred to as frequency domain OCT systems.

All types of OCT imaging units 458 can include an OCT light source 410, an OCT reference mirror 413 and a beam splitter 417. Among the sequential OCT systems, for the (a) type time domain OCT, the OCT light source 410 can be a narrow band laser and the reference mirror 413 movable for z-scanning. For the (b) type swept source OCT, the reference mirror need not be movable as the wavelength of the light

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source 410 is varied. For (c) parallel OCT systems, the OCT light source 410 can emit a broadband imaging light.

The OCT imaging beam can be guided by the OCT beam x-y scanner 459, directed to the eye via an objective 454 and a docking unit 455. The OCT x-y scanner 459 can scan the OCT imaging beam in the eye in the x and y directions. In sequential OCT systems the beam is z scanned by moving either the reference minor 413 or by sweeping the wavelength of the OCT light source 410. In parallel OCT systems, no z-scanning is performed, as the different wavelengths carry the imaging information corresponding to different z depths essentially simultaneously.

In all these system, the OCT imaging beam returned from the eye can be unified with the reference beam returning from the OCT reference mirror 413 at the beam splitter 417. This unified beam carries the imaging information in a complex interference pattern that is recorded by an OCT camera 420.

For sequential OCT systems this OCT camera 420 can be simple, e.g. including a photodetector. For parallel OCT systems the OCT imaging unit 458 may include a spectrometer, such as a prism or a grating (not shown explicitly) that resolves the broad band imaging light into its different wavelength components, and deflects the different wavelength components to different spatial angles. In some parallel OCT systems the OCT camera 420 may include a linear array of CCD detectors to capture these diverging rays with different wavelength, each carrying interference information, specific for its own wavelength. In others, a two dimensional CCD array can be used. The amplitude of the resolved diverging rays can be recorded in the individual pixels of the CCD array of the OCT camera 420. Some high resolution OCT cameras 420 can involve hundreds or even thousands of pixels.

The imaging process can be controlled by an imaging sync block 470, which may get its sync signal from a later-specified output unit. The image data from the OCT camera 420 can be forwarded to an OCT analyzer 480, synchronized by the imaging sync block 470. In parallel OCT systems the OCT analyzer 480 may include a processor to perform a Fast Fourier Transform (FFT). The FFT converts the interference information of different wavelength components into image information corresponding to different z-depths. After the FFT, the transformed OCT image data represent image information corresponding to a range of z-depths. This transformed OCT image data may be forwarded to a processor 430, which can generate an OCT image and output the generated OCT image towards a display 490.

Next, an OCT scanning-beam-controller system will be described that solves the difficulties of the operation of some existing OCT scanning-beam-controllers which are described next.

In some OCT imaging systems the processor 430 can multitask and perform more than one function in an interleaved, parallel or overlapping manner. To carry out these functions, the processor may perform an "interrupt" by switching from e.g. the task of scanning the beam to another task and back. Such interrupts, however short, can cause problems, since during the time when the scanning is stopped or frozen by the interrupt, the laser beam may remain pointed to the same position. This scanning-freeze can disrupt the timing of the x-y scan, introducing an error and noise into the coordinates of the imaged location. This timing error in the outputted scanning data can lead to delays that may reach 50, 100 or more microseconds: a phenomenon sometimes called jitter. Further, the extended exposure to the laser beam can cause damage to the sensitive eye tissue.

In addition, since the processor typically communicates with input/output agents through a system bus, this output

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mode only provides slow data transfer rates, since several agents may access the bus simultaneously, all demanding a fraction of its cycle time. Further, to manage these competing demands, a portion of the cycle of the system bus is typically taken up by control signals. And if an OCT imaging system is designed to avoid this scanning-freeze by the processor outputting the scanning data to an output unit in a single-task mode, e.g. through a dedicated link, then the processor cannot perform other functions during this outputting step, such as computing the next scanning pattern. All these designs and constraints slow down the performance of such systems considerably.

Implementations of the presently described OCT scanning-beam-controller can overcome these difficulties by employing an efficient design. The OCT scanning-beam-controller can include the processor 430 and an analog input-output board 435. The processor 430 can compute scanning data for a scanning pattern. This scanning data can include e.g. a sequence of x-y coordinates where the OCT imaging beam will be directed in the target region in the course of scanning. For sequential, z-scanning OCT systems, the scanning data can include x-y-z coordinates. As described above, the OCT scanning pattern can be a wide variety of patterns, including lines, arcs, loops, circles, spirals, raster and grid patterns.

The processor 430 can compute the scanning data, as well as perform its other described functions in connection to a storage medium that stores a computer code or instruction set to facilitate these functions of the processor.

The analog input-output board 435 can include a local or dedicated memory controller 440, also referred to as a direct memory access engine 440, or DMA engine 440. The DMA engine/memory controller 440 can manage a transfer of the computed scanning data, indirectly or directly, from the processor 430 toward a data buffer 450. The data buffer 450, coupled to the local memory controller 440 can store the scanning data and output the scanning data towards an output digital-analog converter 460, or output DAC 460. The output DAC 460 can be coupled to the data buffer 450 and can (i) convert selected outputted scanning data to analog scanning signals, and (ii) output the scanning signals towards the OCT beam x-y (or x-y-z) scanner 459.

FIG. 11 illustrates an implementation of the OCT scanning beam-controller. The processor 430' can be coupled to a bus 432, such as a PCI bus 432. The OCT scanning-beam-controller can also include a processor memory 433. The processor 430' can output the computed scanning data to the processor memory 433. The dedicated DMA engine 440' can transfer the scanning data from the processor memory 433 to the data buffer 450' which can be e.g. a first-in-first-out (FIFO) memory. The FIFO buffer memory 450' can store the scanning data and output the stored scanning data to the output DAC 460' when prompted. In some implementations, the processor can output the scanning data to the analog input-output board 435 through a dedicated memory bus or local bus instead of a PCI bus 432. In other implementations, there can be even a direct connection between the processor and the DMA engine 440'.

In relation to the above described problems with other systems, embodiments of the present OCT scanning-beam-controller offer a fast scanning operation as (i) the FIFO memory 450' can output the stored scanning data in an uninterrupted manner; (ii) the output mode can be a fast data transfer mode, such as a burst mode; and (iii) the output can be performed without sending the scanning data through the shared bus 432, the processor memory 433, or the processor 430'.

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For all these reasons, the outputting of the scanning data will not be interrupted by competing tasks, or slowed down by the slow data transfer characterizing the shared bus 432.

Further, since the FIFO memory 450' drives the outputting of the scanning data, the processor 430' is free to perform other functions in parallel with the data output, such as processing an image, or computing new scanning data corresponding to a scanning pattern, or performing a control function.

In addition, the output of the scanning data by the data buffer 450' to the output DAC 460' is not slowed down by an interrupt by the processor 430 or another system agent either since the output proceeds from the data buffer 450' through a dedicated channel on the analog input-output board 435 instead of the shared bus 432. Such implementations can reduce the jitter considerably, such as keeping it below 50, 40, or even 20 microseconds.

In some implementations, the output DAC 460' can convert the received digital scanning data into analog scanning signals and output the scanning signals to x and y galvo-controllers 56a and 56b, or some other types of scanning-controllers that control x and y galvo mirrors, or redirector elements, to scan the OCT imaging beam according to the scanning pattern, coded in the scanning data. Some implementations may have an integrated x-y galvo-controller that controls a minor capable of rotating around two axes.

The output DAC 460' can also output synchronizing signals to the imaging sync block 470' coupled to the OCT imaging camera 420 to record the returned OCT imaging beam synchronously with the scanning of the OCT imaging beam. The synchronizing signals can be based on synchronizing data, inserted by the processor 430' into the scanning data.

In addition, the imaging step 120 can include computing homing data corresponding to a homing pattern connecting an ending point of a first imaging step to a starting point of a subsequent second imaging step. This step can be useful in implementations where the first imaging step ends by simply stopping the output of the scanning data, thus leaving the scanning x and y galvos 56a-b in a non-standard position and the imaging beam pointed to a non-standard target point. This non-standard point is typically different from the starting point of the subsequent second imaging step, thus necessitating the "homing" of the x and y galvos 56a-b by computing and outputting homing data, so that the imaging beam can start the subsequent second imaging step from a well-defined starting point.

As an example, the first imaging step may include scanning the x and y coordinates of the imaging beam along a first circle of a first radius. If the second imaging step includes scanning along a second circle of a second radius, then the first imaging step can be followed by computing homing data that define a path from the endpoint of the first circular scan with the first radius to the starting point of the second circular scan with the second radius.

Such implementations can avoid moving the imaging beam back to a standard point, e.g. to a center, origin, or otherwise unbiased point, thus saving additional time and further accelerating the scanning operation.

The computing of the homing data can be also useful in implementations where at the end of the first imaging step the x and y galvos 56a and 56b are returned to a neutral position, as it facilitates the computing of the starting position of a second imaging step in relation to the neutral position.

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In some implementations, the speed of the output of the output DAC 460/460' can be so fast that an operating speed of the imaging system 457 can be limited by an integration time of the OCT camera 420.

In some implementations, the output DAC 460/460' can output the scanning signals at a rate within one of the following ranges: 1 Hz-1 MHz, 100 Hz-1 MHz, or 1 kHz-100 kHz.

In some implementations, the rate of output for the scanning signals can be adjustable according to the requirements of the imaging task and pattern.

Once the imaging step 120 is completed, the alignment-improving step 130 can include providing a verbal command to a patient based on the image of the internal structure of the eye, such as the lens 5.

The alignment-improving step 130 can also include providing a fixation light beam, asking the patient to look at the fixation light, and adjusting the fixation light based on the image provided by the imaging step 120. The fixation light can be provided into the surgical eye, through the main optical pathway of the laser surgical system 50, or through a separate fixation light system. In some cases the fixation light can be provided to the non-surgical eye.

The alignment-improving step 130 can be started (i) before the docking unit 55/200 makes contact with the eye; (ii) after the docking unit 55/200 makes contact with the eye but before an application of a vacuum; or (iii) after an application of a partial vacuum in relation to the docking unit 55/200 that still allows some degree of alignment modification.

The partial vacuum, or suction, can be applied, for example, through a suction ring or suction skirt, which can be part of the docking unit 55/200. The suction can be applied after the eye was brought into physical contact with the eye.

The docking method 100 can be performed as part of a surgical process or a diagnostic process. In other implementations, the docking method 100 can be part of an imaging procedure, which is not part of a surgical or a diagnostic procedure, such as an identification process.

The steps 110-140 can involve program codes or instruction sets that are stored in the imaging system 57. The code can be stored e.g. in a dedicated memory or in a memory that is part of another functional block. The aligning step 110 can involve a code stored in a memory related to the video microscope 56. The imaging step 120 can involve storing the scanning patterns or scanning data generated by the processor 430 in a dedicated or integrated memory, or storing scanning data in the data buffer 450. The alignment-improving step 130 can include using a memory unit for storing the generated image to help improving the alignment of the docking unit 55 with the lens of the eye 1 in relation to the generated image. The docking step 140 can also use a stored program to guide and control the docking unit 200 docking with the eye.

FIG. 12 illustrates that an implementation of a fast imaging method 500 can include:

A step 510 of computing scanning control data by the processor 430/430';

A step 520 of storing the scanning control data into the processor memory 433 by the processor 430;

A step 530 of setting up the dedicated memory controller 440/440' for a scanning operation by defining operation parameters, such as a scanning output rate;

A step 540 of transferring scanning control data from the processor memory 433 to the data buffer 450/450' at least partially under the control of the dedicated memory controller 440/440';

A step 550 of notifying the processor 430/430' by the dedicated memory controller/DMA engine 440/440' that the transfer of the scanning control data has been completed;

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A step 560 of instructing the dedicated memory controller 440/440' by the processor 430/430' to start fast output of the scanning control data;

A step 570 of transferring the scanning control data from the data buffer 450/450' to the output DAC 460/460' at least partially under the control of the dedicated memory controller 440/440', the output DAC 460/460' converting the digital scanning control data to analog scanning control signals, and the output DAC 460/460' outputting the analog scanning control signals to the x and y scanners 56a and 56b, and to the sync block 470;

A step 580 of notifying the processor 430/430' by the dedicated memory controller 440/440' that the output process is complete.

In the step 570, the transferring the scanning control data from the data buffer 450/450' can be performed in a fast transfer mode, such as a burst mode, or a page mode, or any similarly fast transfer modes.

In the step 570, the transferring of the scanning control data from the data buffer 450/450' can be performed without sending the scanning control data through the bus 432 that connects the local memory controller 440, the processor 430, and the processor memory 433.

In the step 570, the transferring step can also include transferring the scanning control data in parallel with the processor 430 processing an image or computing scanning data corresponding to a scanning pattern.

In the step 570, the transferring step can also include transferring the scanning data without an interrupt by another system agent, thereby keeping a jitter of the scanning data below 50, 40, or 20 microseconds.

In an implementation 600 of the above method 500, the above steps can be organized into the following steps:

A step 610 of computing scanning control data by a processor can include the step 510;

A step 620 of storing the scanning control data into a data buffer partially by a local memory controller can include the steps 520, 530, 540, and 550;

A step 630 of transferring the scanning control data from the data buffer in a fast transfer mode to a converter-output module can include the steps 560 and elements of the step 570; and

A step 640 of outputting scanning signals to scanning controllers, the scanning signals converted from the scanning control data by the converter-output module can include elements of the step 570.

While this specification contains many specifics, these should not be construed as limitations on the scope of any invention or of what may be claimed, but rather as descriptions of features specific to particular embodiments. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or variation of a subcombination.

The invention claimed is:

1. A docking method for an ophthalmic system, the method comprising:

aligning a docking unit of the ophthalmic system and an eye;

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generating an image of an internal structure of the eye by an optical coherence tomographic imaging system after aligning the docking unit and the eye; improving an alignment of the docking unit with the internal structure of the eye in relation to the generated image; and docking the docking unit to the eye with the improved alignment the generating the image step comprising: computing scanning data by a processor corresponding to a scanning pattern; storing the scanning data in a dedicated data buffer; transferring the scanning data by the dedicated data buffer to an output module partially under the control of a dedicated memory controller; outputting scanning signals by the output module to one or more scanners based on the scanning data; and scanning an imaging beam with the one or more scanners according to the scanning signals.

2. The method of claim 1, the aligning the docking unit step comprising:

using a first imaging system to align a target pattern of the ophthalmic system in relation to a feature of the eye.

3. The method of claim 2, wherein:

the first imaging system is one of a microscope or a video microscope;

the target pattern of the ophthalmic system includes at least one of a center of a contact lens, a center of the docking unit, a docking circle, or a docking cross-hair; and the feature of the eye is at least one of

a center of a region of an iris, a pupil, a cornea, a limbus, or a lens; or

a circular formation related to a region of the iris, the pupil, the cornea, the limbus or the lens.

4. The method of claim 1, the improving an alignment step comprising:

extracting position information regarding the internal structure of the eye from the generated image; and adjusting a position of at least one of the eye or the docking unit in relation to the extracted position information.

5. The method of claim 1, the improving an alignment step comprising:

extracting orientation information regarding the internal structure of the eye from the generated image; and adjusting an orientation of at least one of the eye or the docking unit in relation to the extracted orientation information.

6. The method of claim 1, the computing the scanning data step comprising:

implementing a scanning pattern that includes at least one of a linear pattern, a circular pattern, an oval pattern, a loop pattern, an arc pattern, a raster pattern, an x-y pattern, a crosshair pattern, a star pattern, a spiral pattern, and a pattern with outlying points.

7. The method of claim 1, the computing the scanning data step comprising:

including synchronizing signals into the scanning data by the processor.

8. The method of claim 1, the computing the scanning data step comprising:

computing homing data corresponding to a homing pattern connecting a starting point of the scanning pattern to a previously set point.

9. The method of claim 1, the storing the scanning data step comprising:

storing the scanning data in a processor memory; and

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transferring the stored scanning data from the processor memory to the dedicated data buffer partially under the control of the dedicated memory controller.

10. The method of claim 9, wherein:

the dedicated memory controller comprises a direct memory access engine; and

the dedicated data buffer comprises a first-in-first-out memory.

11. The method of claim 1, the transferring the scanning data step comprising:

outputting the scanning data by the dedicated data buffer to the output module in a fast data transfer mode.

12. The method of claim 1, the transferring the scanning data step comprising:

outputting the scanning data from the dedicated data buffer without sending the scanning data through at least one of a bus connecting the dedicated memory controller and the processor,

the processor memory, or

the processor.

13. The method of claim 1, the transferring the seaming data step comprising:

outputting the scanning data in parallel with the processor performing at least one of

processing an image,

computing scanning data corresponding to a scanning pattern, or

performing a control function.

14. The method of claim 1, the transferring the scanning data step comprising:

receiving the scanning data by the output module without an interrupt by another system agent,

thereby keeping a jitter of the scanning data below 40 microseconds.

15. The method of claim 1, the outputting the scanning signals step comprising:

converting the scanning data into analog scanning signals by the output module, wherein the output module includes a digital-analog converter.

16. The method of claim 1, the scanning an imaging beam step comprising:

receiving the outputted scanning signals by a scanning controller and an imaging synchronizer, wherein

the scanning signals comprise synchronizing signals;

repeatedly adjusting the one or more scanners by the scanning controller according to the scanning signals to scan the imaging beam; and

repeatedly synchronizing an imaging camera by the imaging synchronizer according to the synchronizing signals.

17. The method of claim 16, wherein:

the scanning controller comprises at least one galvo-controller; and

the imaging synchronizer comprises at least one ophthalmic coherence imaging camera controller.

18. The method of claim 1, wherein:

an integration time of an image recording device is a limiting factor of an operating speed of an imaging system.

19. The method of claim 1, the outputting the scanning signals step comprising:

outputting the scanning signals at a rate within one of the following ranges:

1 Hz-1 MHz, 100 Hz-1 MHz, or 1 kHz-100 kHz.

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20. The method of claim 1, the outputting the scanning signals step comprising:

adjusting an output rate of the output of the scanning signals.

21. The method of claim 1, the improving the alignment step comprising at least one of:

providing a verbal command to a patient to move his eye,

moving the patient's head,

moving a surgical bed the patient is resting on,

moving the patient's eye,

moving the docking unit via moving a gantry or an articulated arm, and

using a gripper to move the eye,

based on the image of the internal structure of the eye.

22. The method of claim 1, the improving the alignment step comprising:

adjusting at least one of a fixation beam or a directing light to improve the alignment of the eye and the docking unit;

and

directing the patient to follow the fixation beam or the directing light with his eye.

23. The method of claim 1, the improving the alignment step comprising:

starting the improving the alignment step

before the docking unit makes contact with the eye,

after the docking unit makes contact with the eye but before an application of a partial vacuum to the docking unit, or

after an application of a partial vacuum.

24. The method of claim 1, the docking step comprising:

sensing a distance between a reference point of the docking unit and an outer layer of the eye; and

lowering the docking unit according to the sensed distance.

25. The method of claim 24, wherein:

the reference point is adjustable.

26. The method of claim 1, the docking step comprising:

bringing the docking unit into physical contact with the eye; and

applying suction through a portion of the docking unit after the docking unit makes physical contact with the eye.

27. An imaging controller for an ophthalmic system, comprising:

a processor that computes scanning data for a scanning pattern of an optical coherence tomographic imaging system;

a local memory controller that partially manages a transfer of the computed scanning data from the processor to a dedicated data buffer, wherein

the dedicated data buffer is configured to store the scanning data and to output the scanning data; and

an output digital-analog converter, coupled to the dedicated data buffer that converts selected scanning data to analog scanning signals and outputs the scanning signals to the optical coherence tomographic imaging system.

28. The imaging controller of claim 27, the local memory controller comprising:

a direct memory access engine.

29. The imaging controller of claim 27, the dedicated data buffer comprising:

a first-in-first-out memory that outputs the stored scanning data in a fast data transfer mode.

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30. The imaging controller of claim 27, further comprising: a processor memory; and a bus, coupled to the processor, the local memory controller and the processor memory, Wherein the processor is configured to output the computed scanning data to the processor memory through the bus; and the local memory controller is configured to transfer the scanning data from the processor memory to the dedicated data buffer through the bus.

31. The imaging controller of claim 30, wherein: the dedicated data buffer is configured to output the scanning data without sending the scanning data through at least one of the bus, the processor memory, or the processor.

32. The imaging controller of claim 27, wherein: the processor is configured to perform at least one of processing an image and computing scanning data, while the dedicated data buffer outputs the scanning data.

33. The imaging controller of claim 27, wherein: the output digital-analog converter is coupled to the dedicated data buffer so that the scanning data, outputted by the dedicated data buffer is received without an interrupt by another system agent, thereby keeping a jitter of the scanning data below 40 microseconds.

34. The imaging controller of claim 27, wherein: the output digital-analog converter is configured to output the scanning signals to x and y scanning controllers to scan an imaging beam; and synchronizing signals to an imaging camera to record a returned imaging beam synchronously with the scanning.

35. A method of controlling an ophthalmic imaging, the method comprising the steps of: computing scanning control data by a processor for an optical coherence tomographic imaging system; storing the scanning control data into a dedicated data buffer partially under the control of a memory controller; transferring the scanning control data from the dedicated data buffer to a signal converter through a dedicated channel; and sending scanning signals to a scanning controller by an output module, wherein the scanning signals are converted from the scanning control data by the signal converter.

36. The method of claim 35, the storing the scanning control data step comprising:

storing the computed scanning control data in a processor memory; and moving the scanning control data from the processor memory to the dedicated data buffer.

37. The method of claim 36, the transferring the scanning control data step comprising:

transferring the scanning data from the dedicated data buffer without sending the scanning data through at least one of a bus connecting the local memory controller and the processor, the processor memory, or the processor.

38. The method of claim 35, the transferring the scanning control data step comprising:

transferring the scanning data in parallel with the processor performing at least one of: processing an image; and

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computing scanning data corresponding to a scanning pattern.

- 39.** The method of claim **35**, the transferring the scanning control data step comprising:
transferring the scanning data without an interrupt by another system agent,
thereby keeping a jitter of the scanning data below 40 microseconds. 5

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- 40.** The method of claim **35**, wherein:
the local memory controller includes a direct memory access engine; and
the dedicated data buffer is a first-in-first-out memory.

* * * * *

EXHIBIT 3



US009849036B2

(12) **United States Patent**
Chaudhary et al.

(10) **Patent No.:** US 9,849,036 B2
(45) **Date of Patent:** *Dec. 26, 2017

(54) **IMAGING-CONTROLLED LASER SURGICAL SYSTEM**(71) Applicant: **ALCON LENSX, INC.**, Aliso Viejo, CA (US)(72) Inventors: **Gautam Chaudhary**, Laguna Hills, CA (US); **Peter Goldstein**, Santa Ana, CA (US); **Imre Hegedus**, Aliso Viejo, CA (US); **Carlos German Suarez**, Tustin, CA (US); **David Calligori**, Rancho Santa Margarita, CA (US); **Michael Karavatis**, San Pedro, CA (US)(73) Assignee: **ALCON LENSX, INC.**, Aliso Viejo, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(63) Continuation of application No. 13/110,352, filed on May 18, 2011, now Pat. No. 9,622,913.

(51) **Int. Cl.**

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A61B 18/00	(2006.01)

(52) **U.S. Cl.**

CPC	A61F 9/00825 (2013.01); A61B 2018/00636 (2013.01); A61F 2009/0087 (2013.01); A61F 2009/00844 (2013.01); A61F 2009/00851 (2013.01); A61F 2009/00889 (2013.01)
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(58) **Field of Classification Search**

CPC	A61F 2009/0087; A61F 9/008; A61F 2009/00851; A61F 2009/00889; A61F 9/00825; A61F 2018/00636; A61F 2009/00844
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See application file for complete search history.

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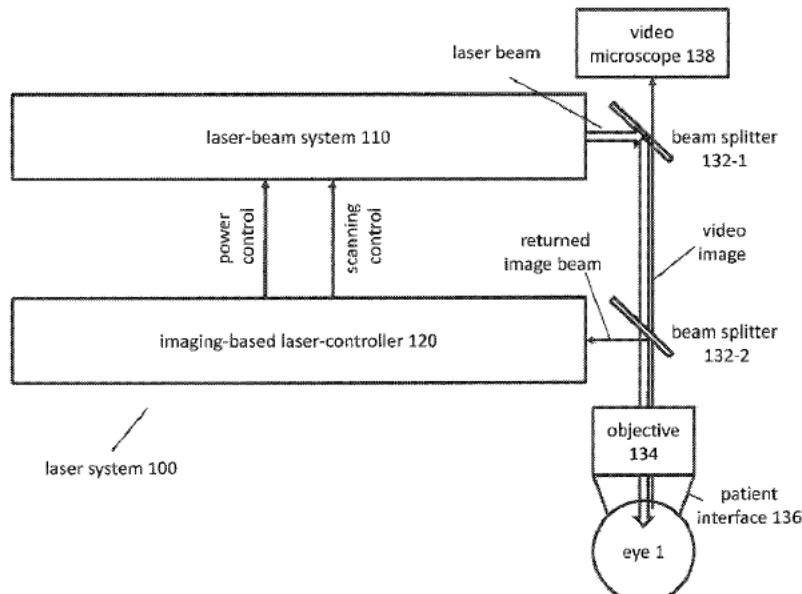
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(57) **ABSTRACT**

An imaging-based laser system can include a laser-beam system, configured to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye, and an imaging-based laser-controller, configured to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

17 Claims, 26 Drawing Sheets

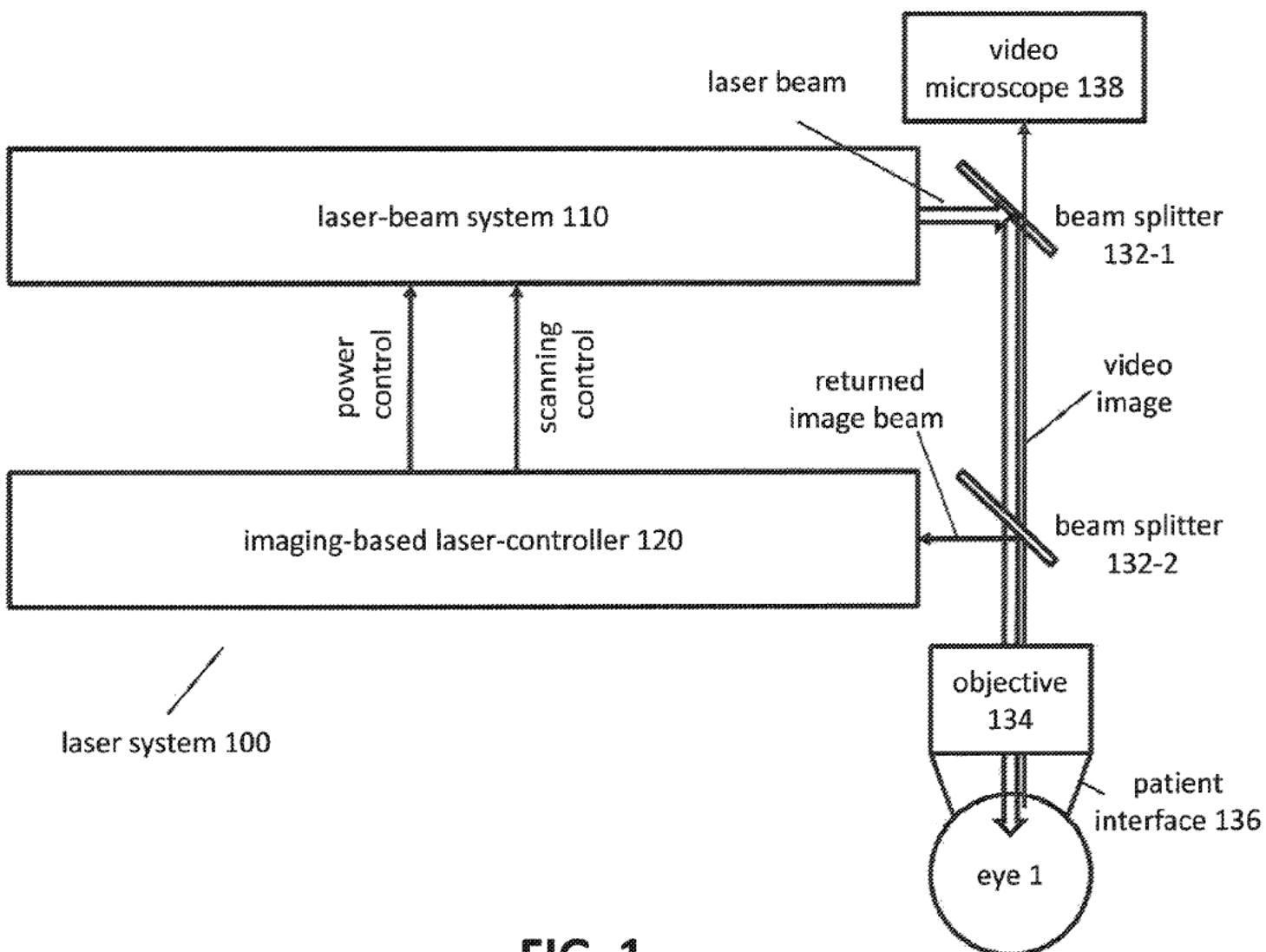


FIG. 1

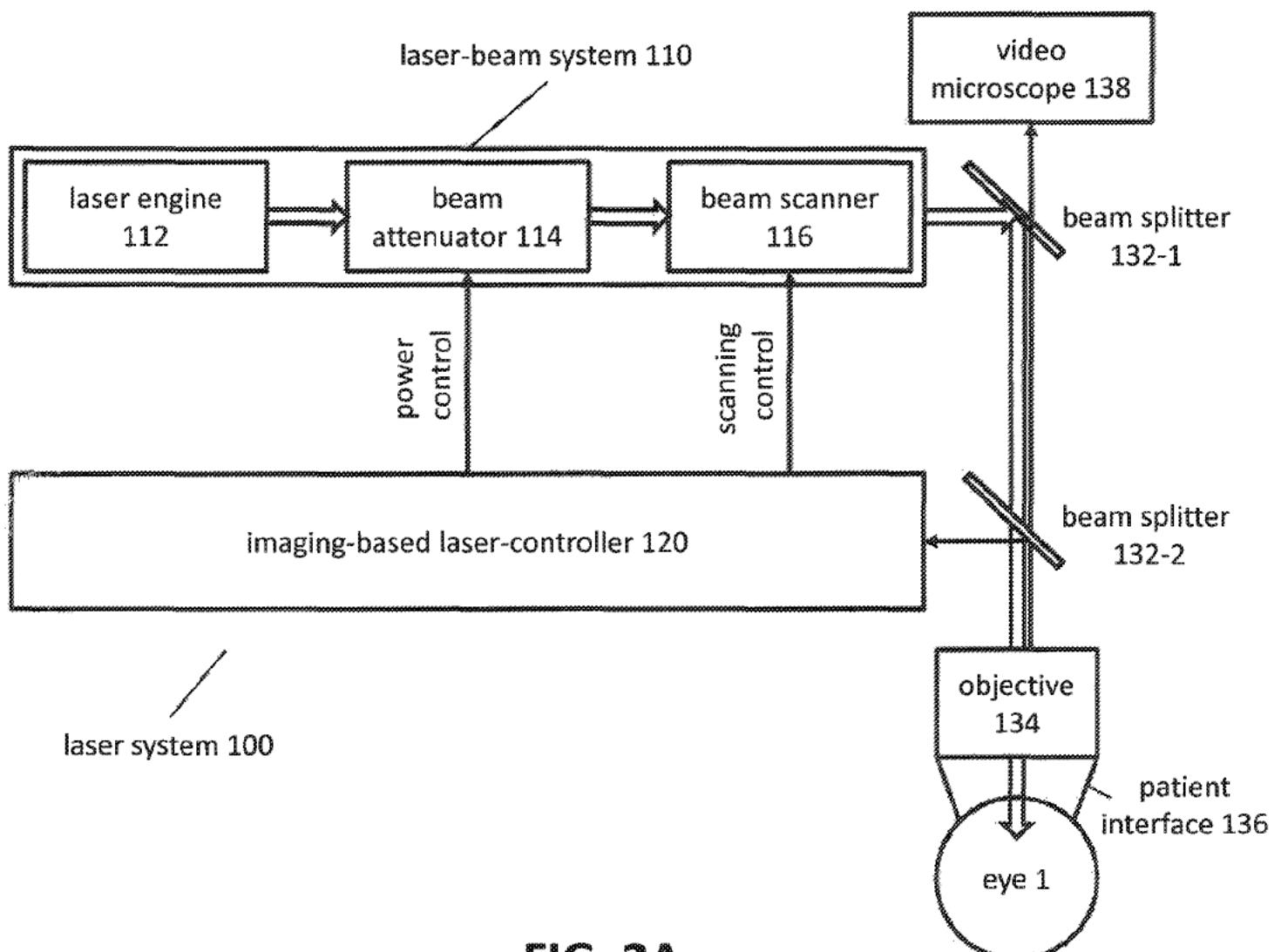


FIG. 2A

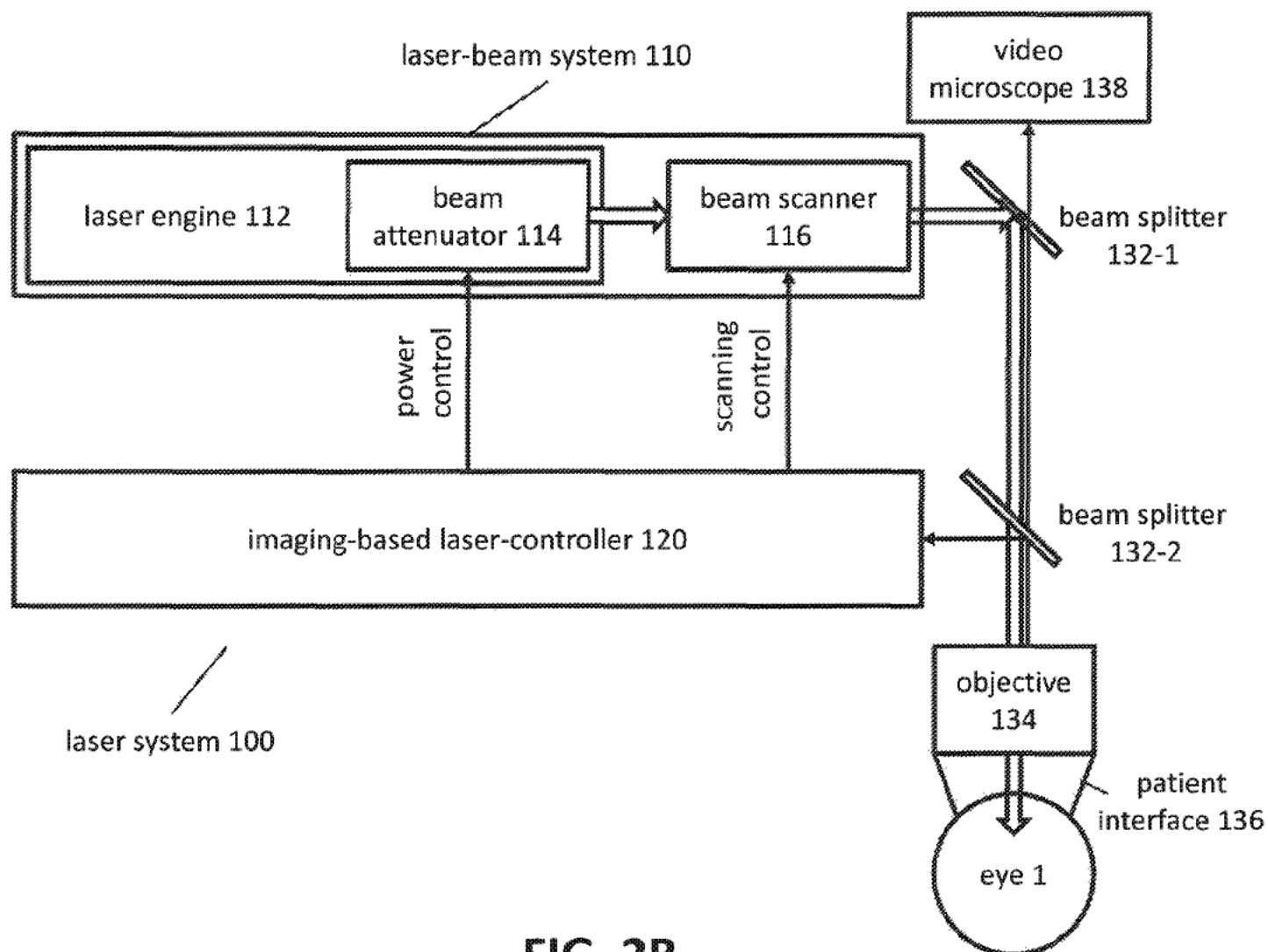


FIG. 2B

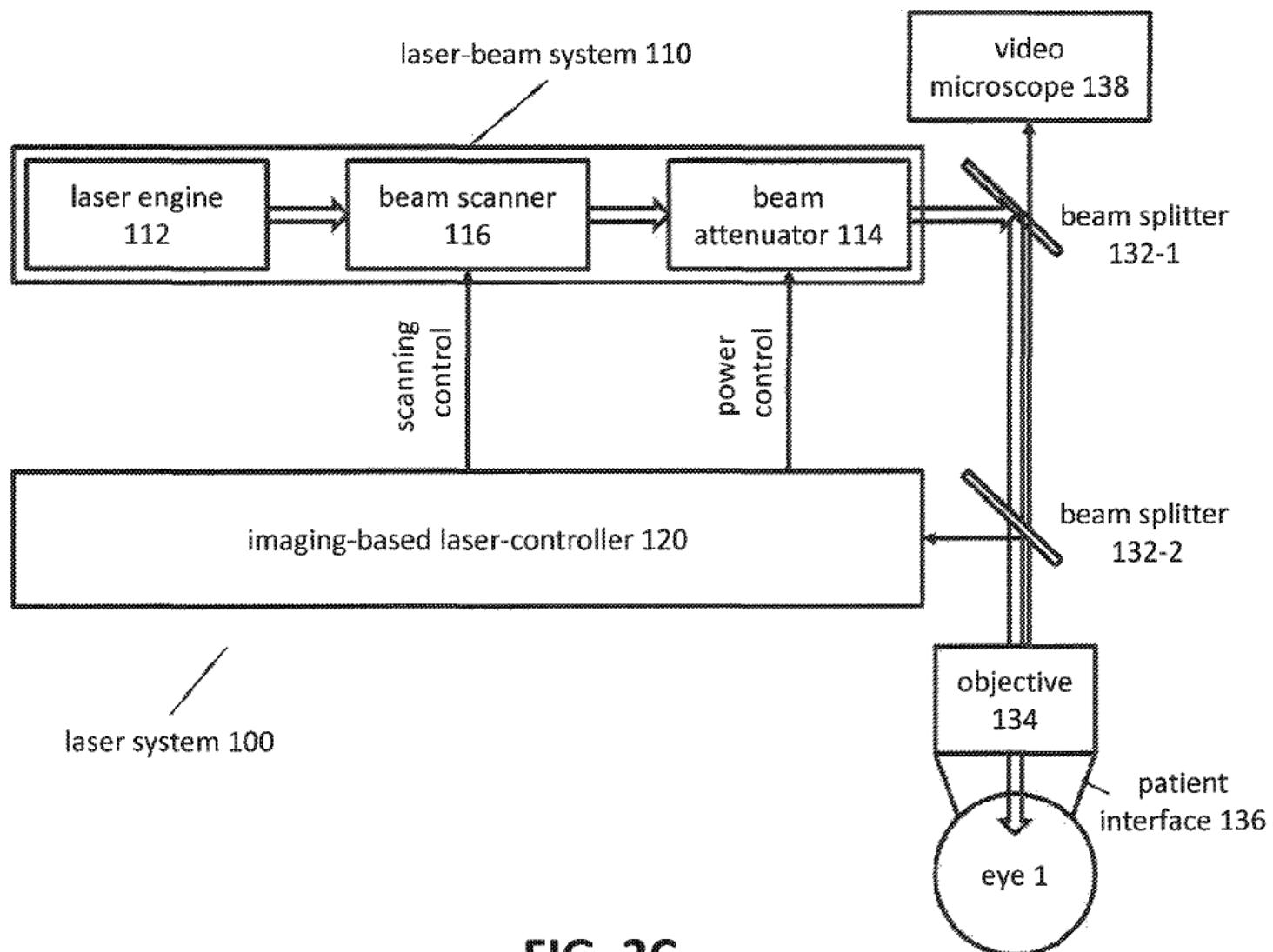


FIG. 2C

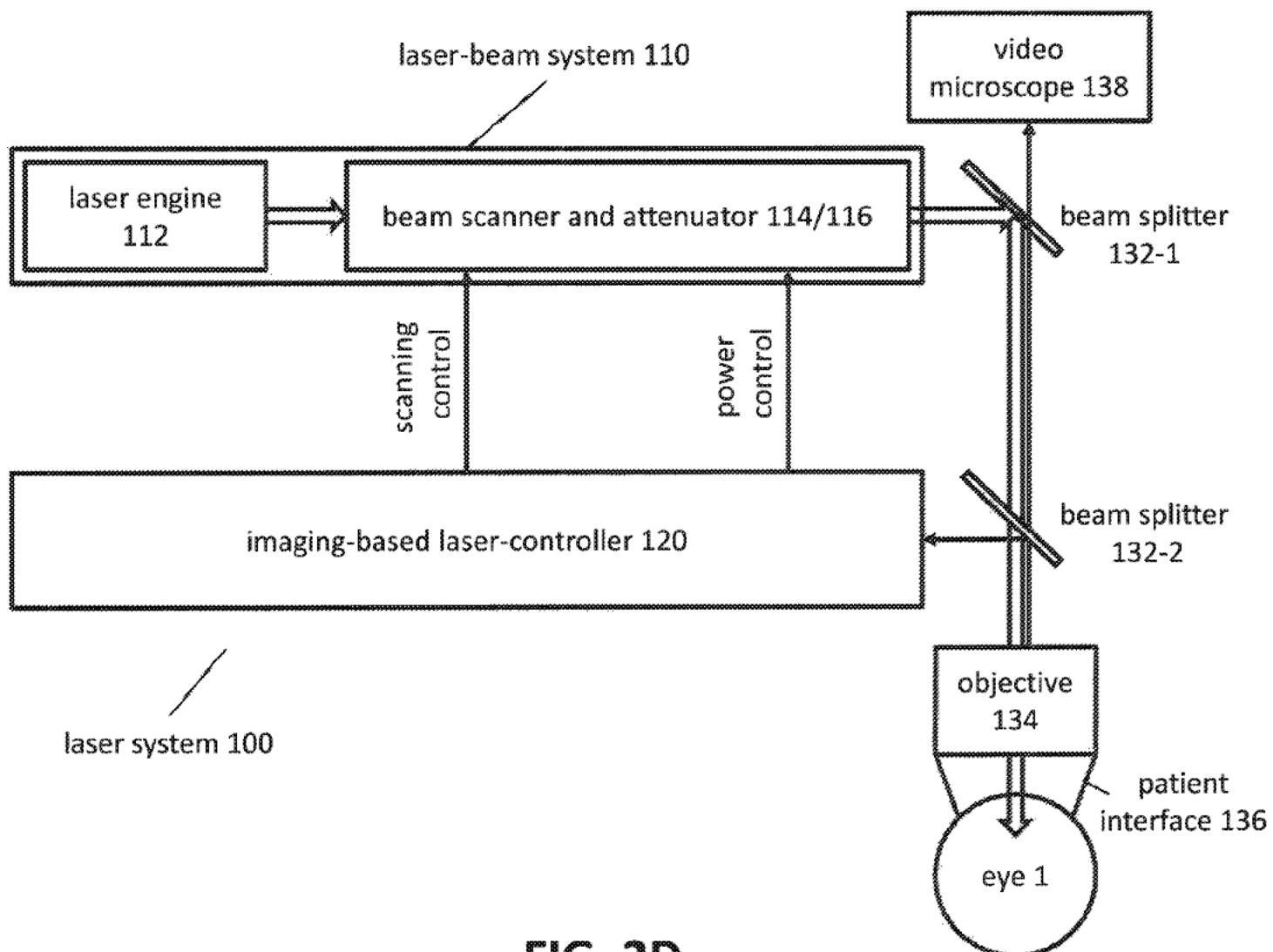


FIG. 2D

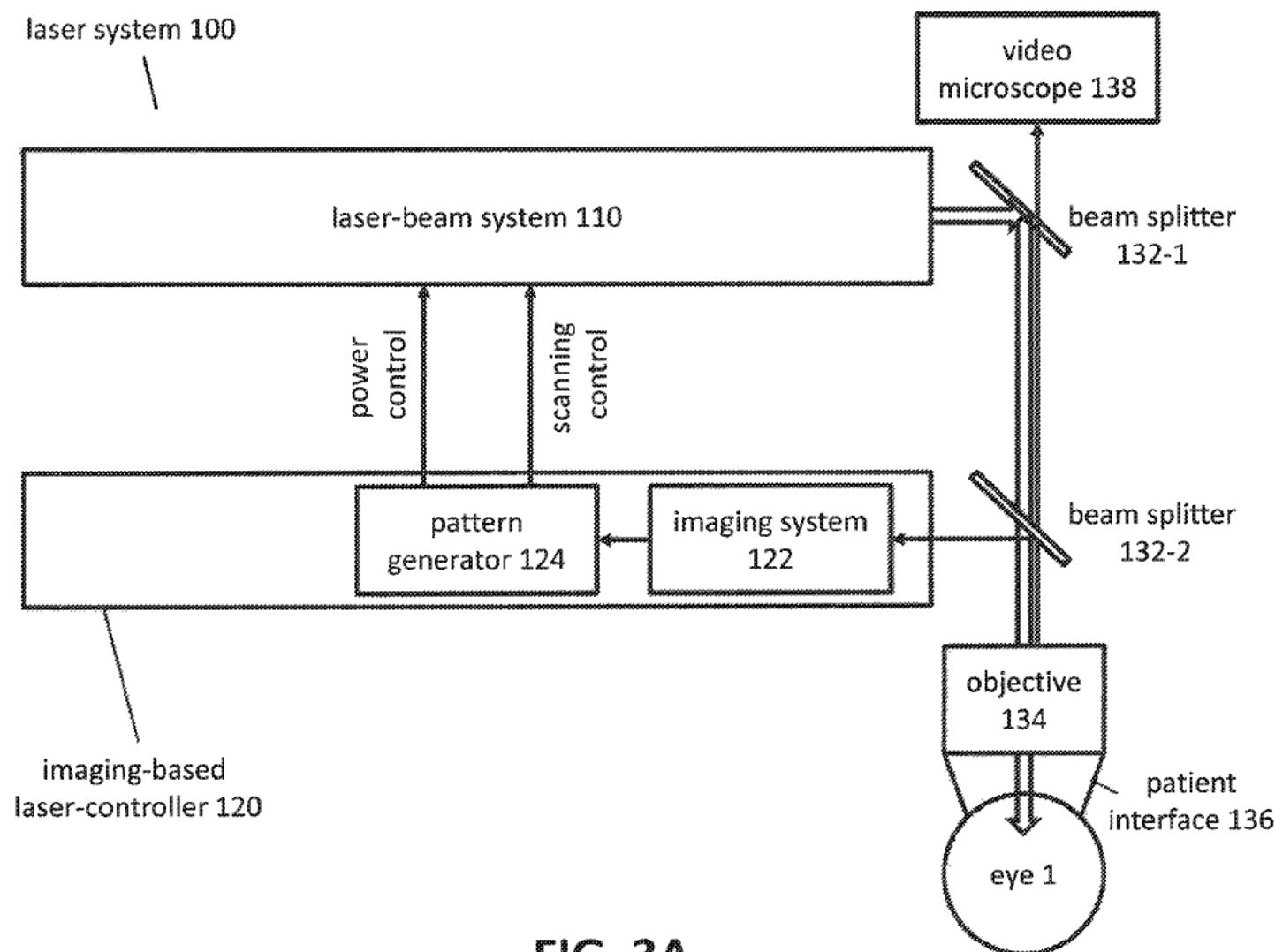


FIG. 3A

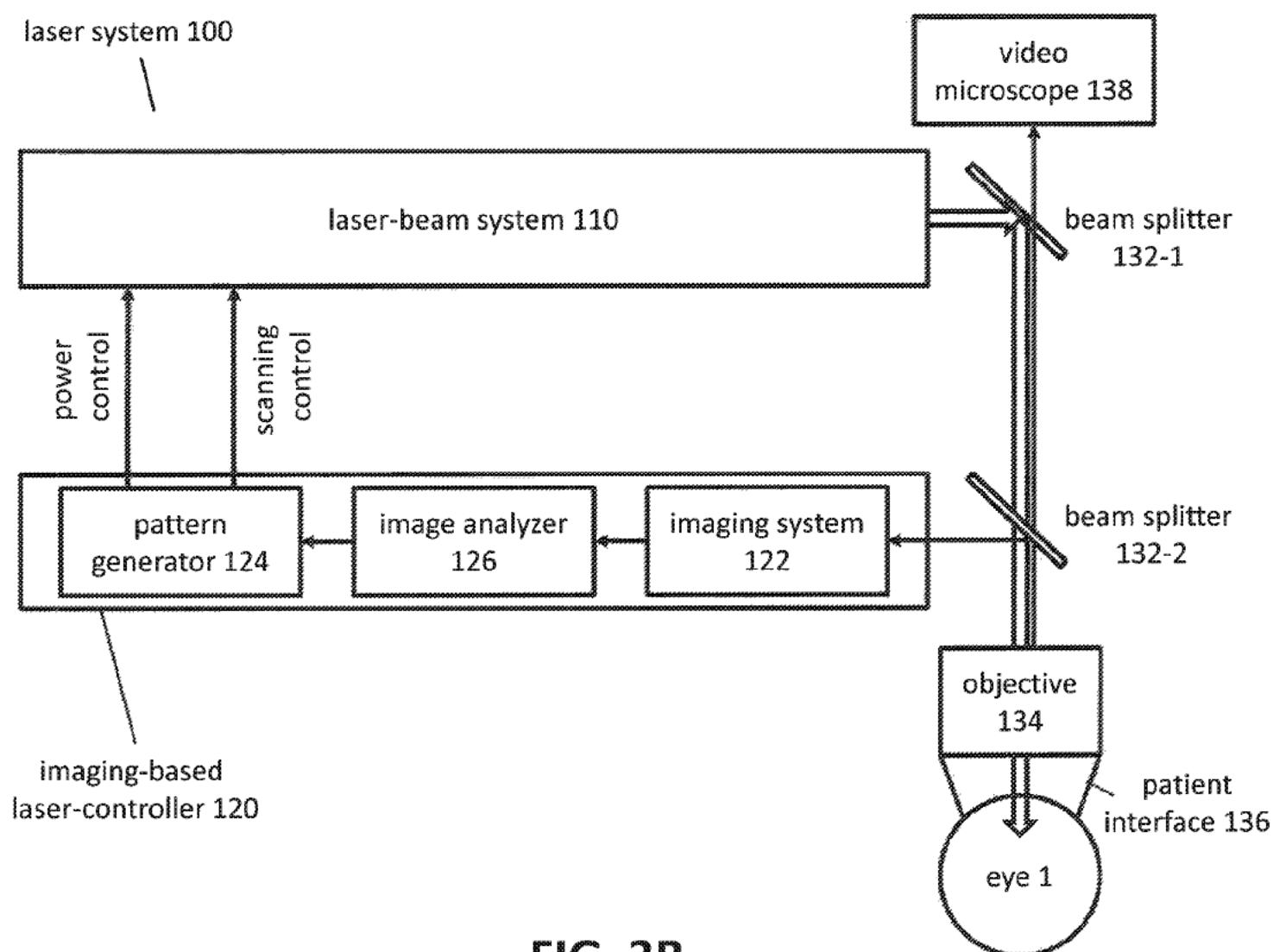


FIG. 3B

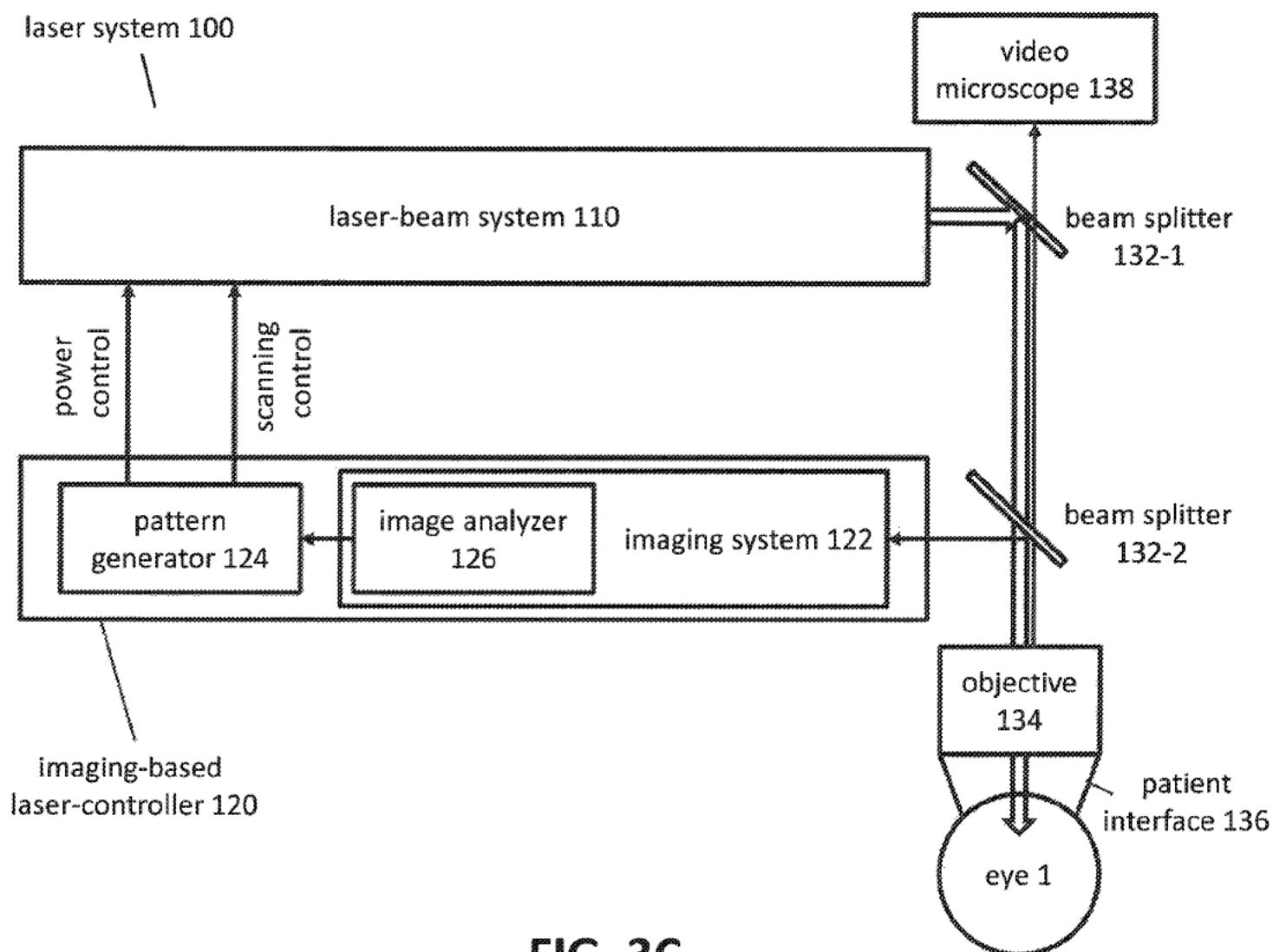


FIG. 3C

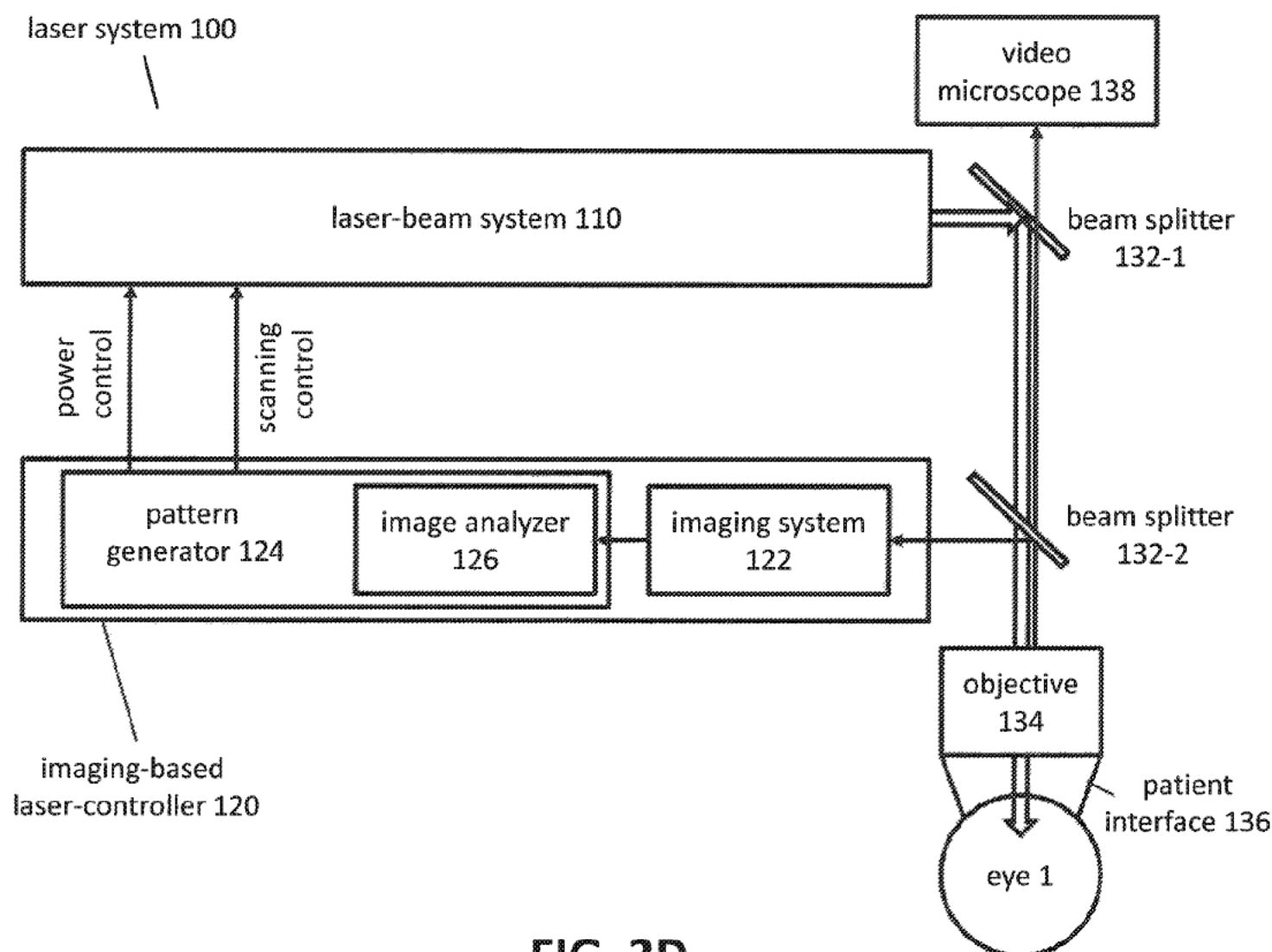


FIG. 3D

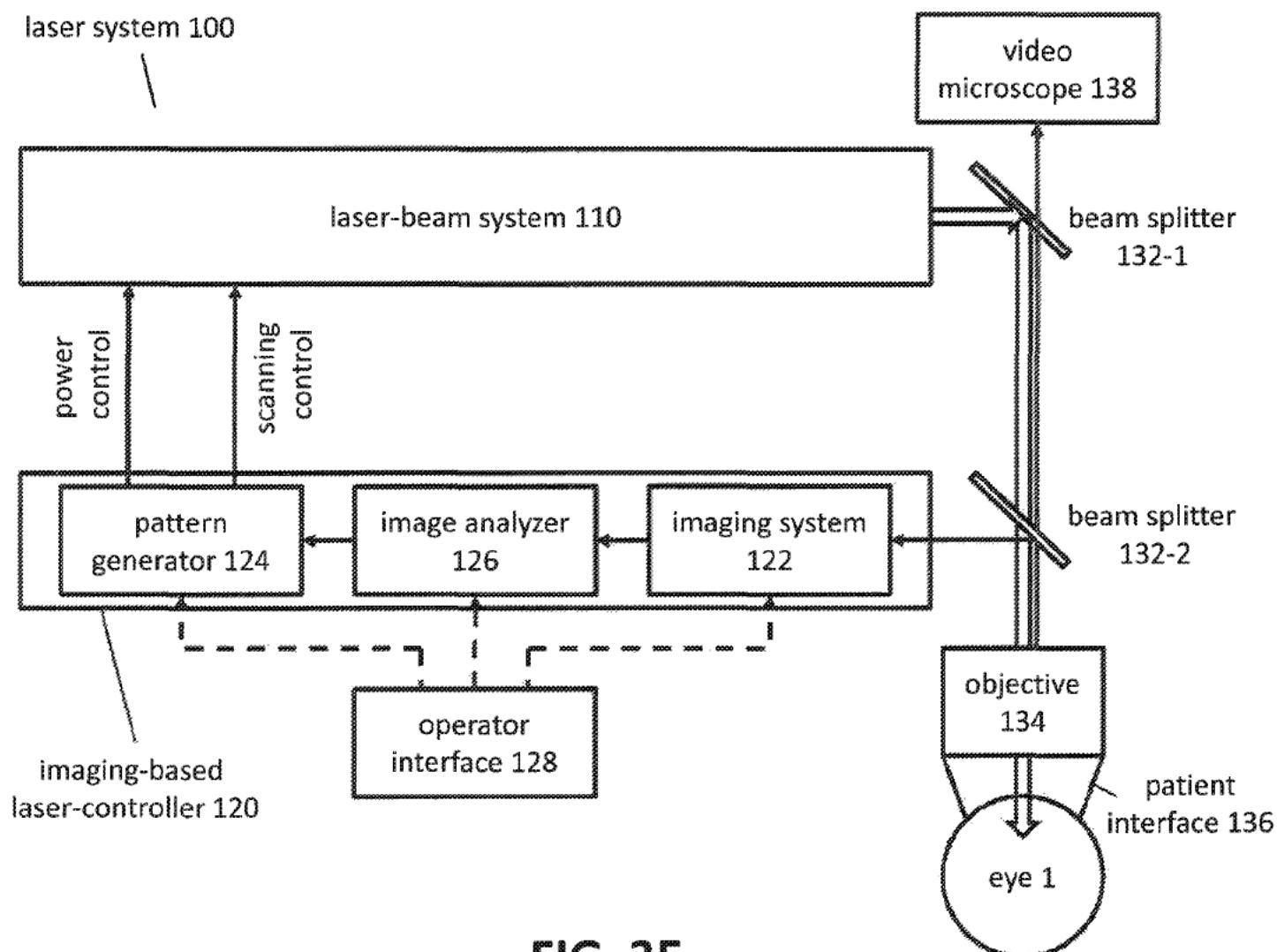


FIG. 3E

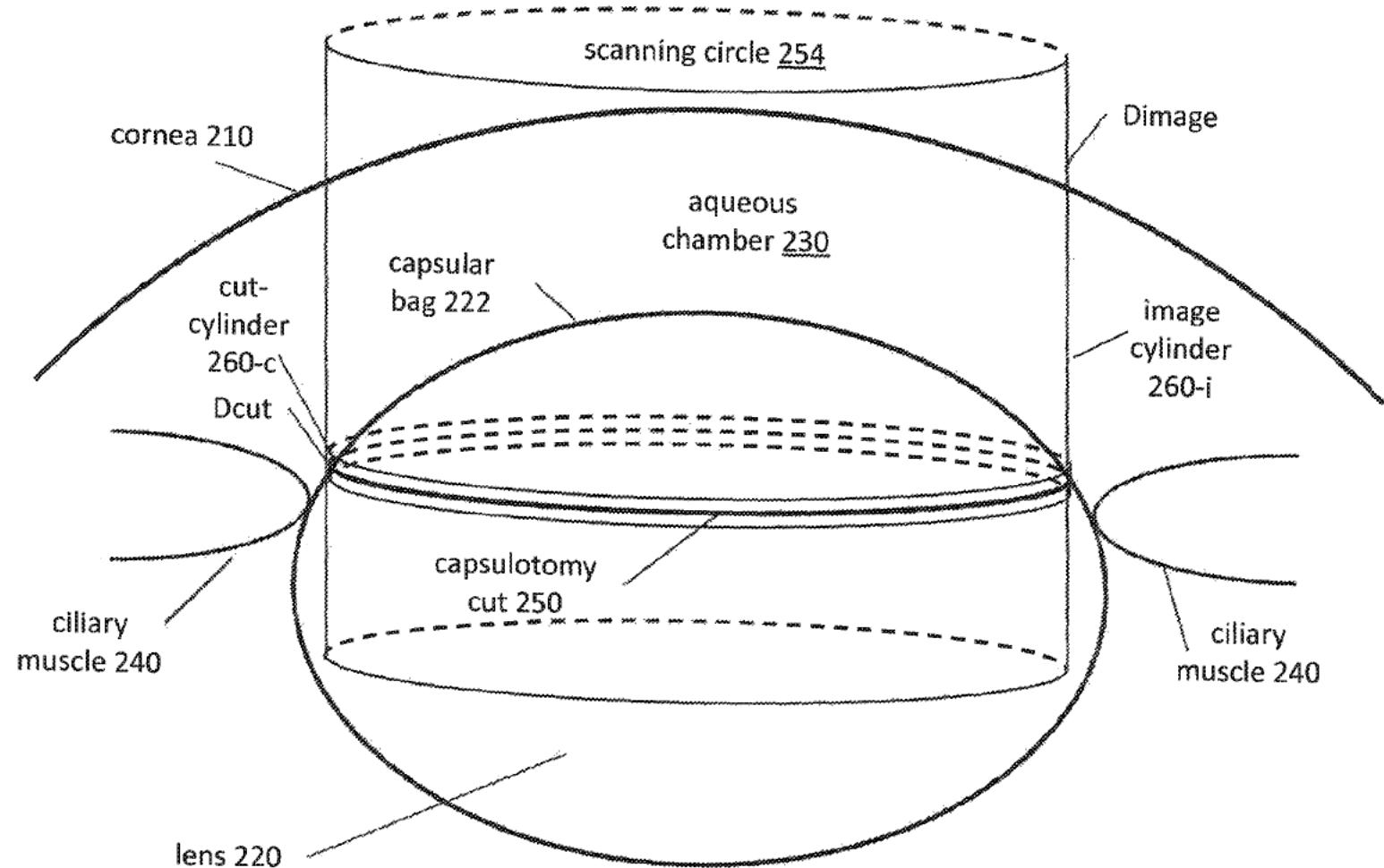


FIG. 4A

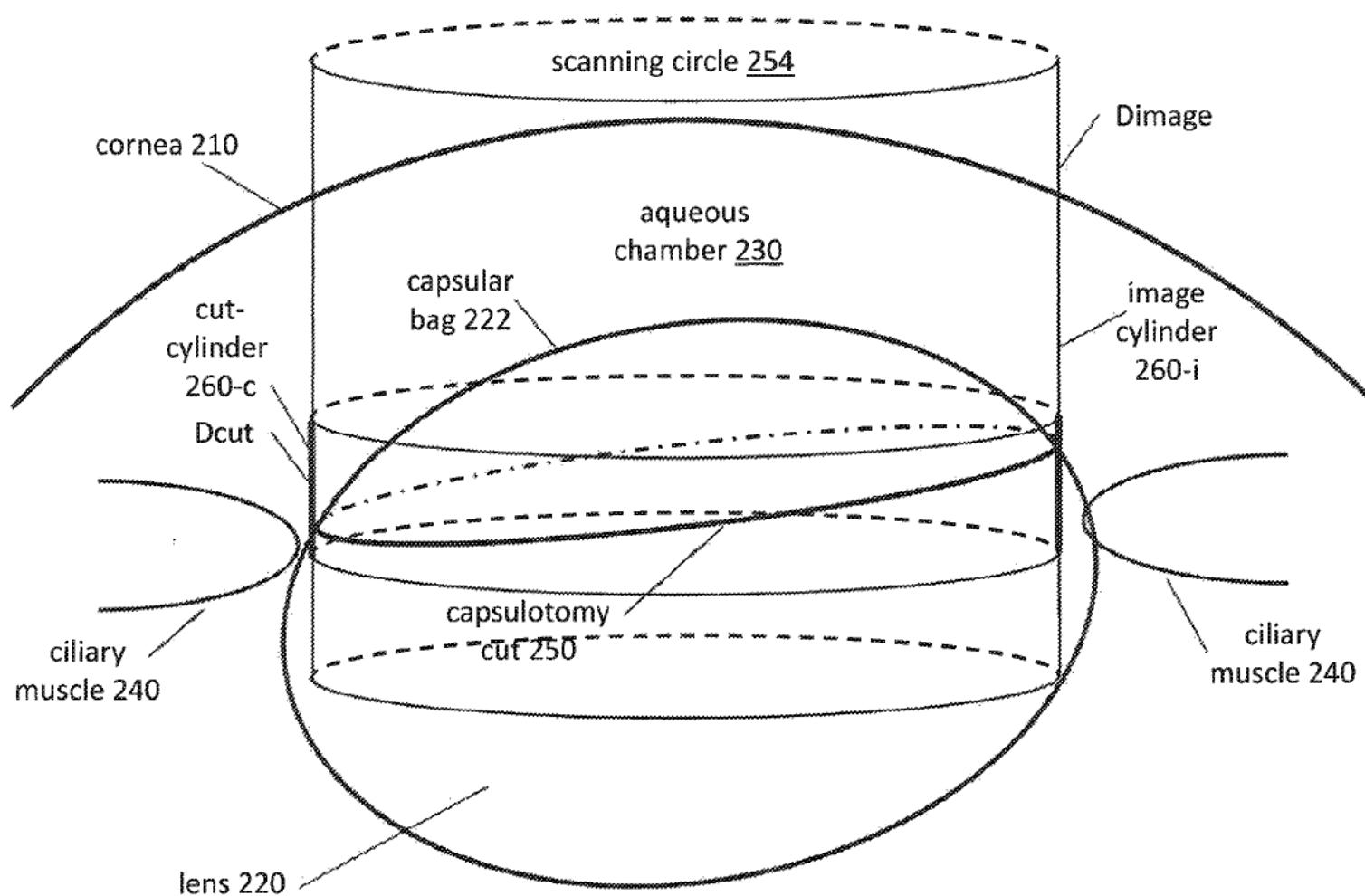


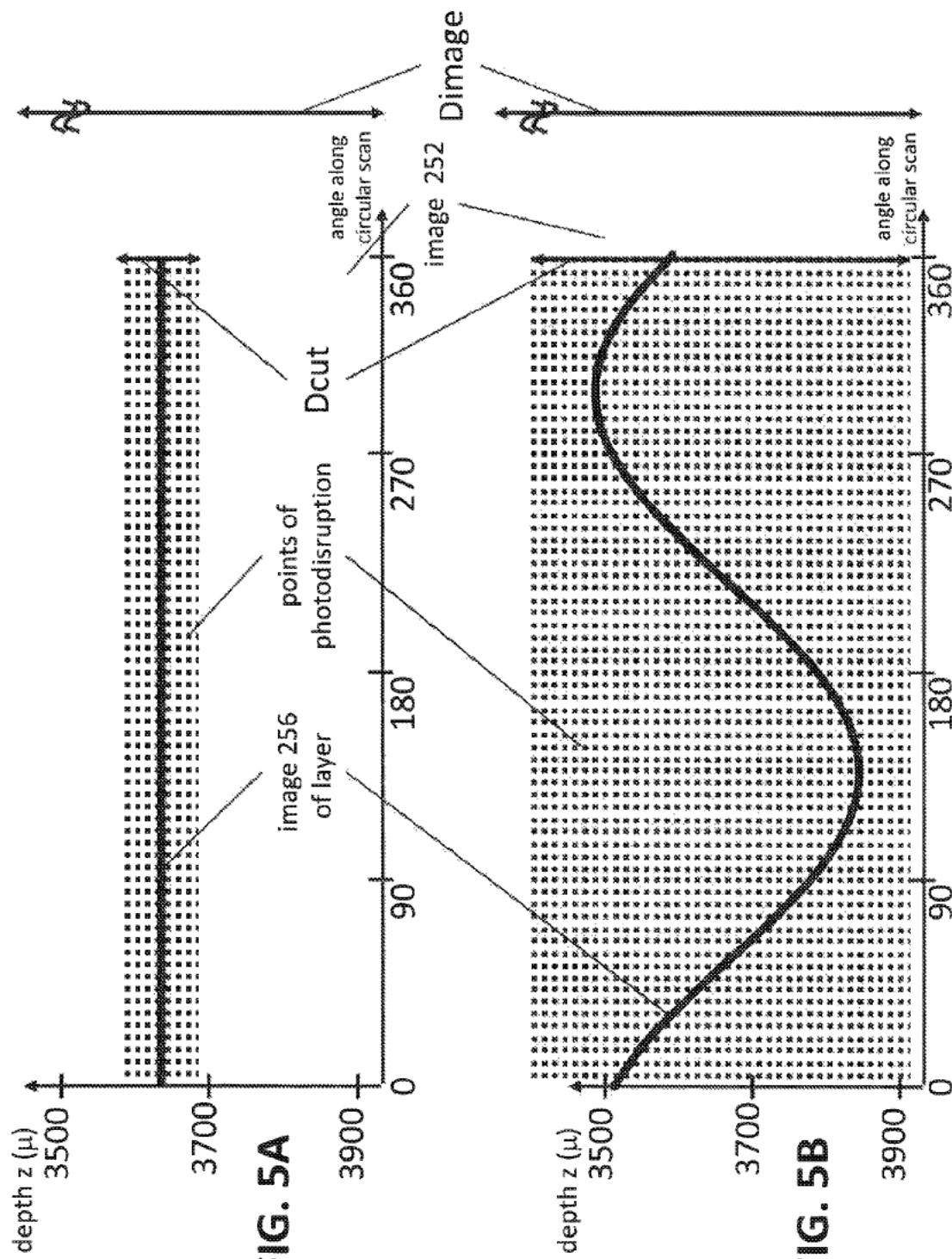
FIG. 4B

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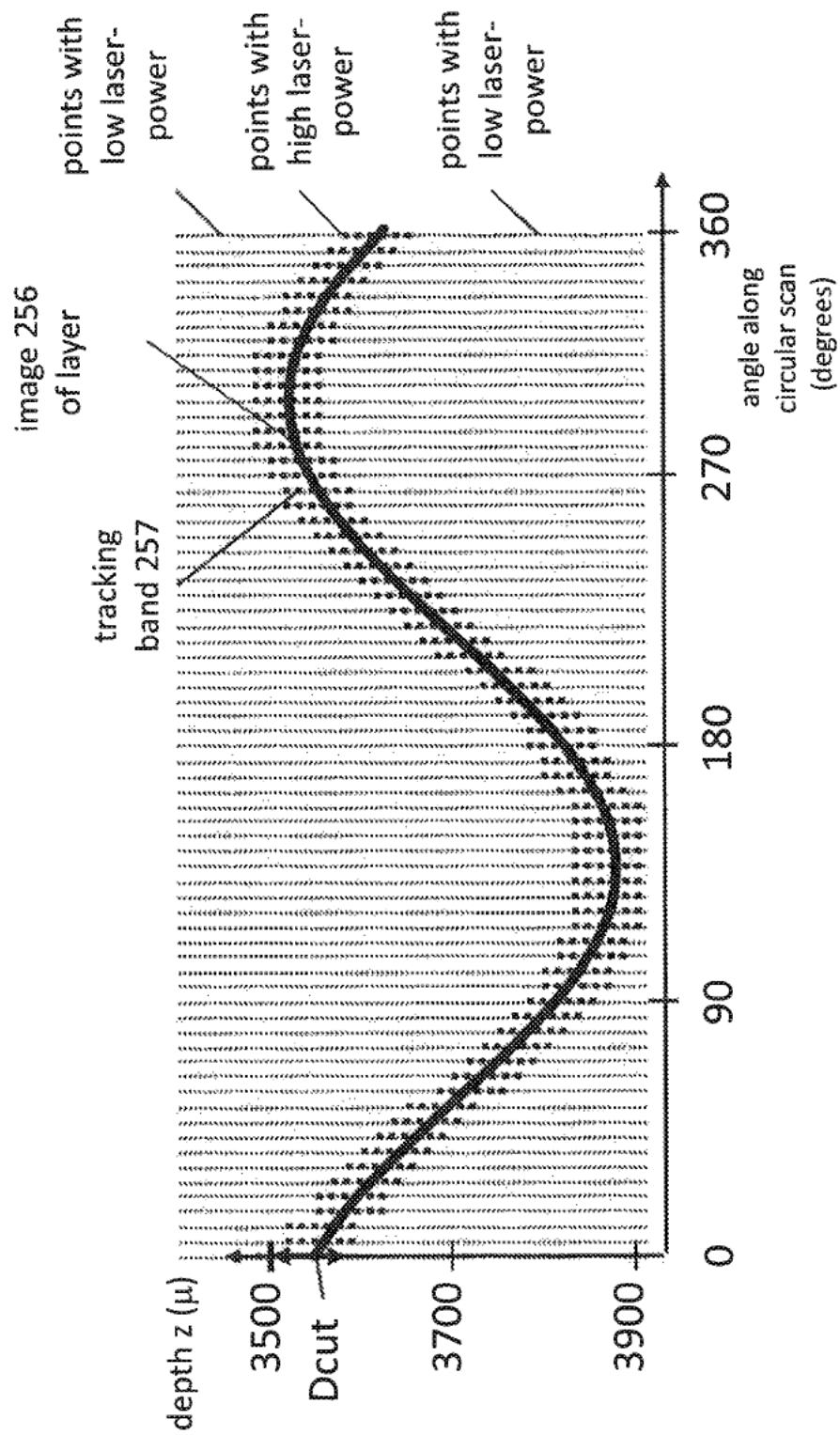


FIG. 6A

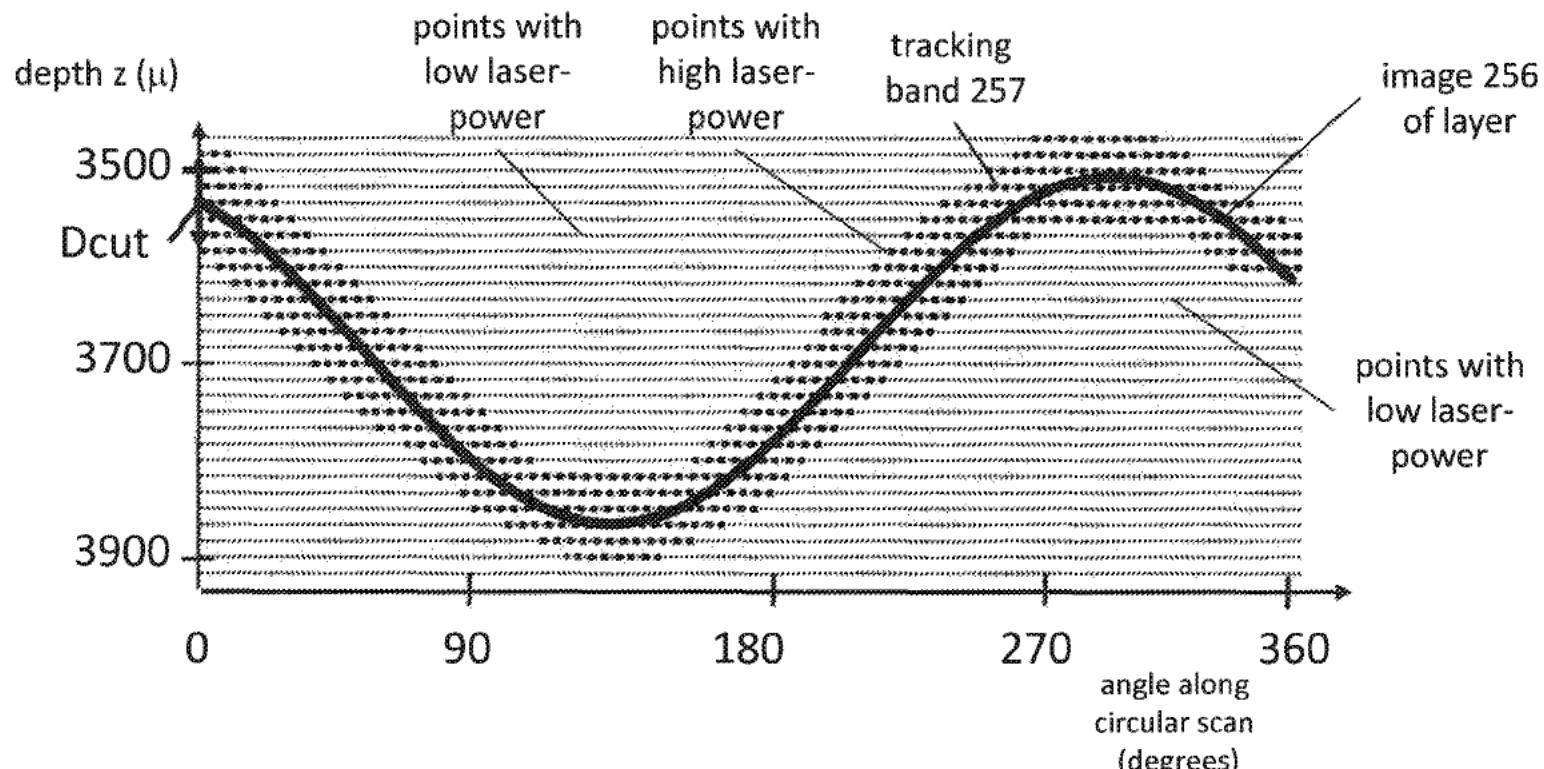


FIG. 6B

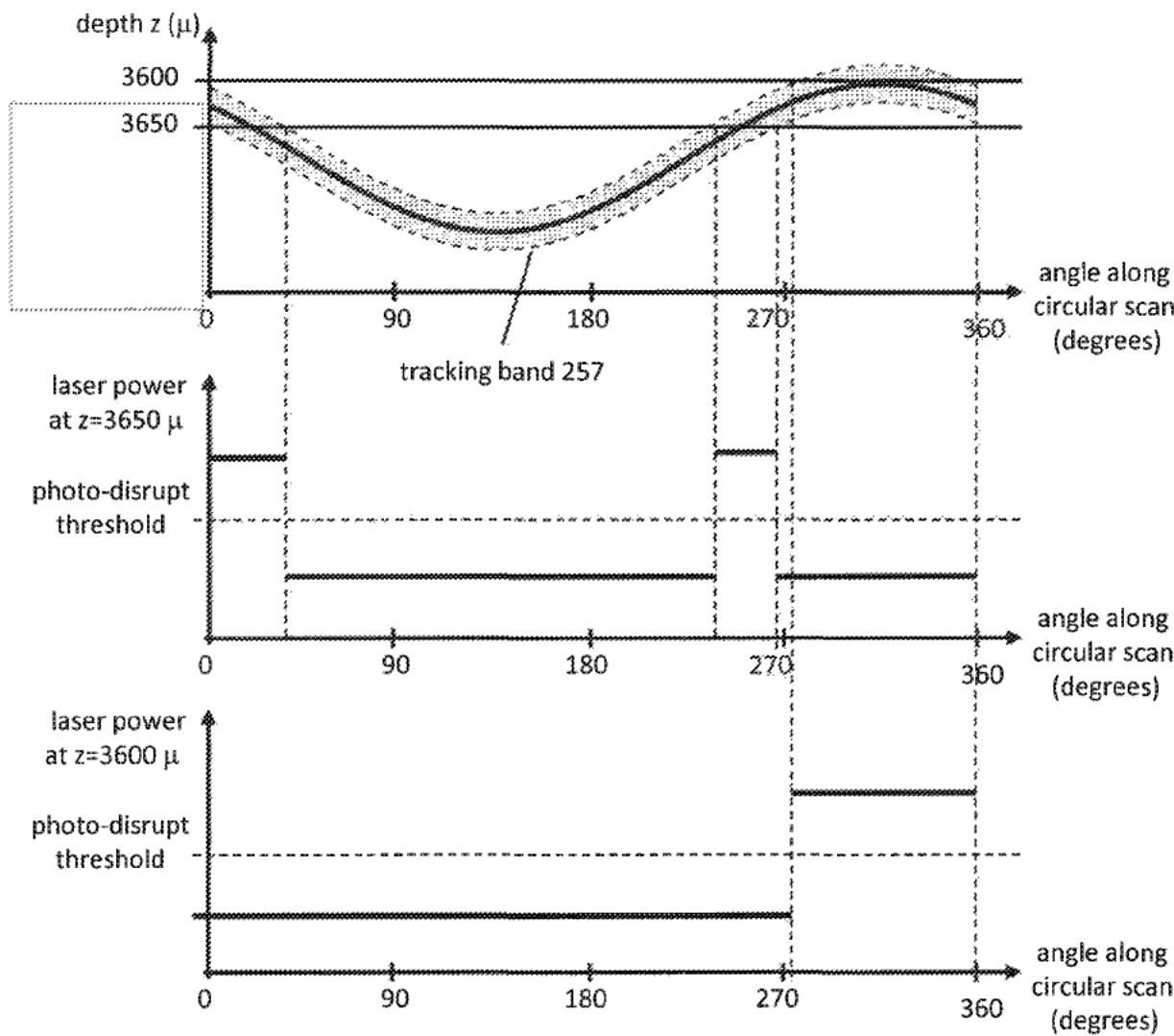


FIG. 6C

FIG. 6D

FIG. 6E

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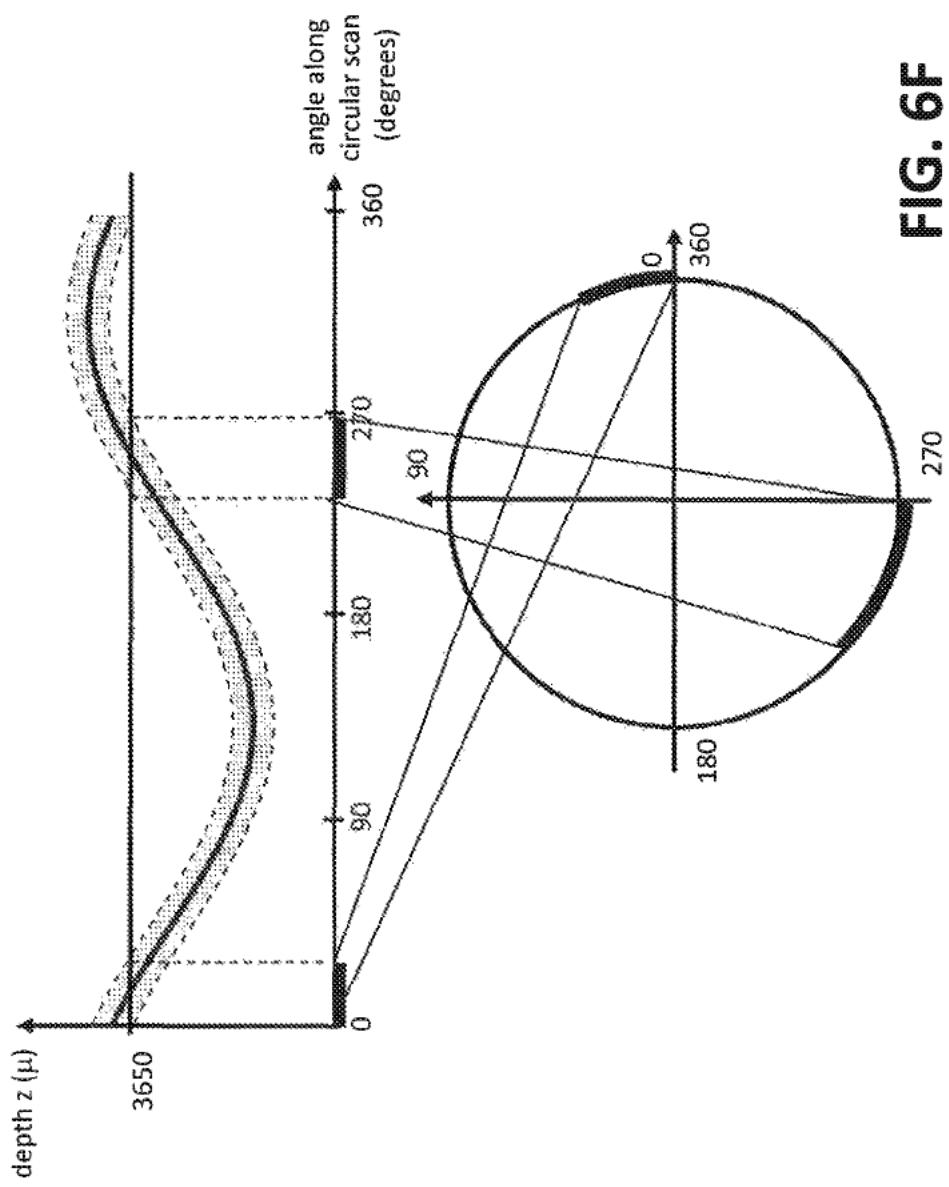


FIG. 6F

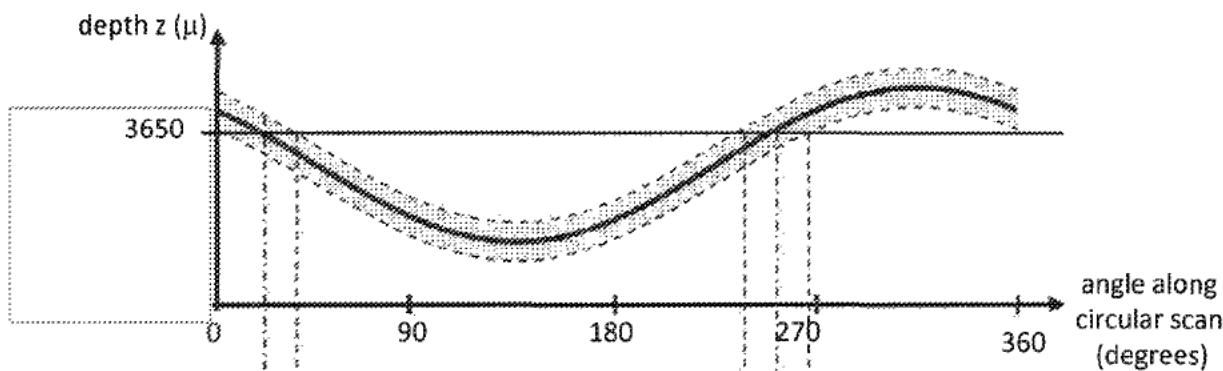


FIG. 6G

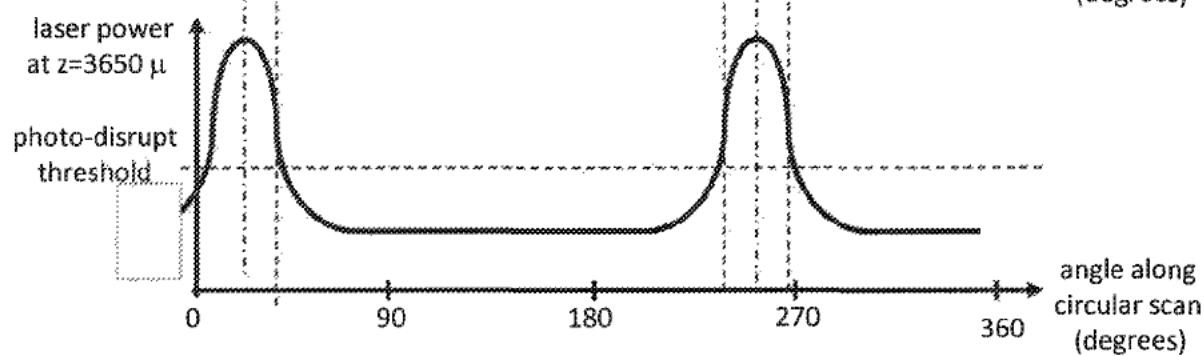
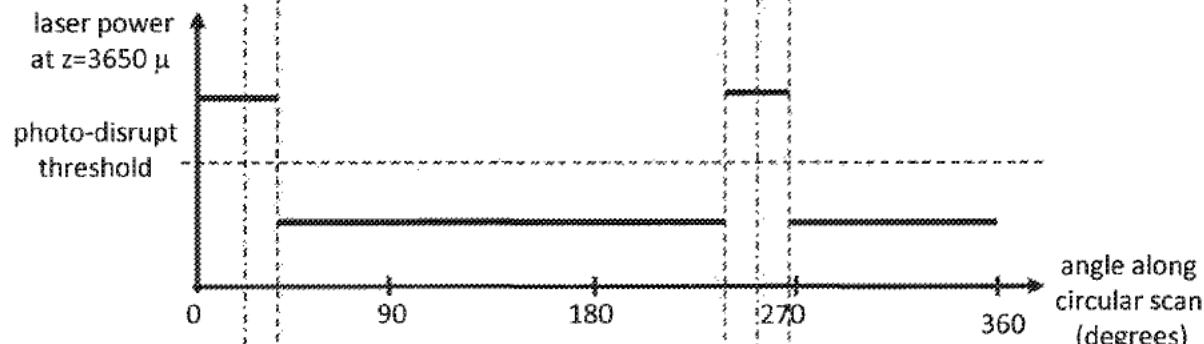


FIG. 6H

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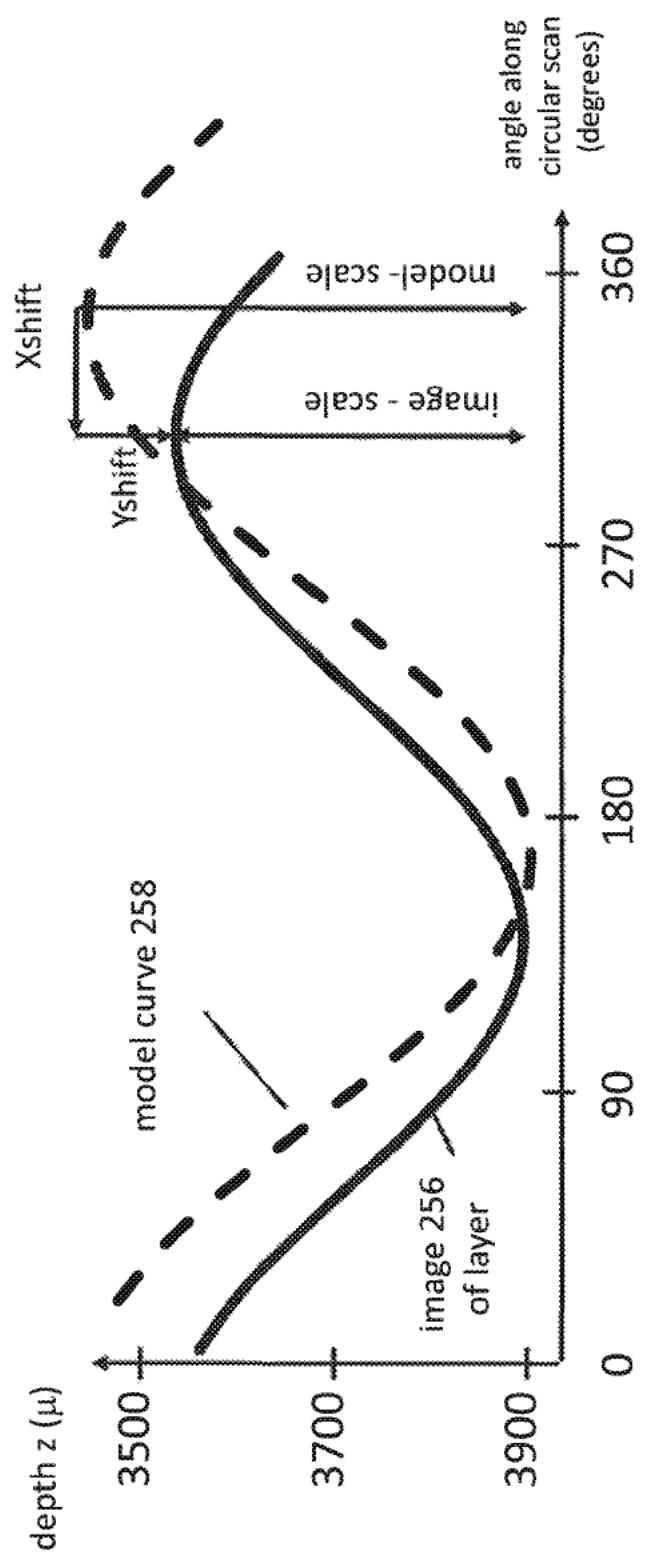


FIG. 7

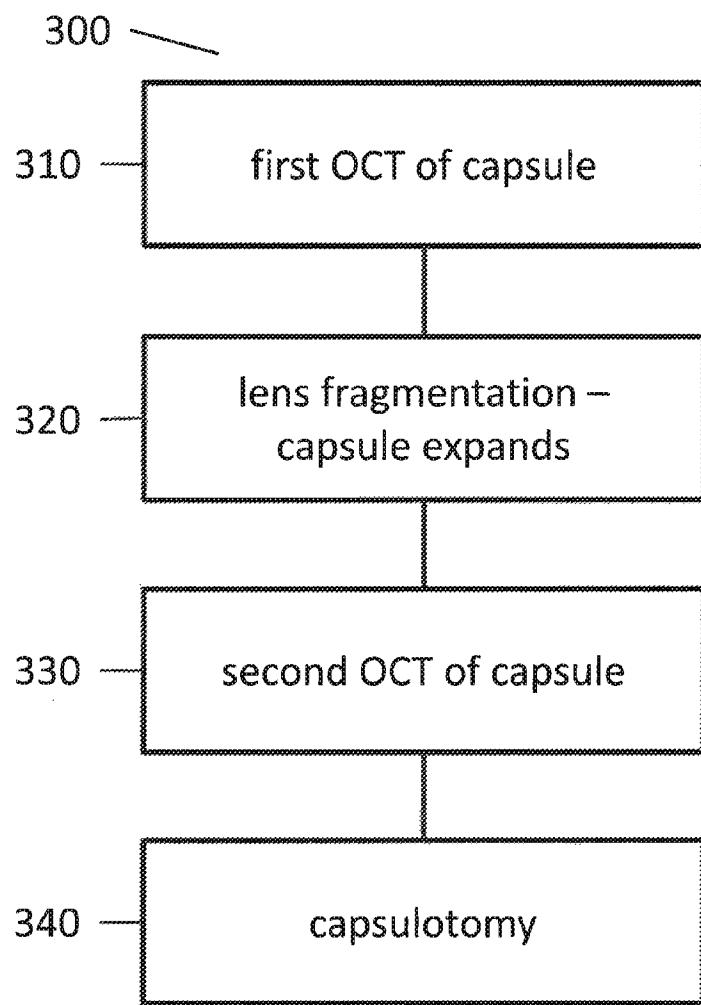


FIG. 8A

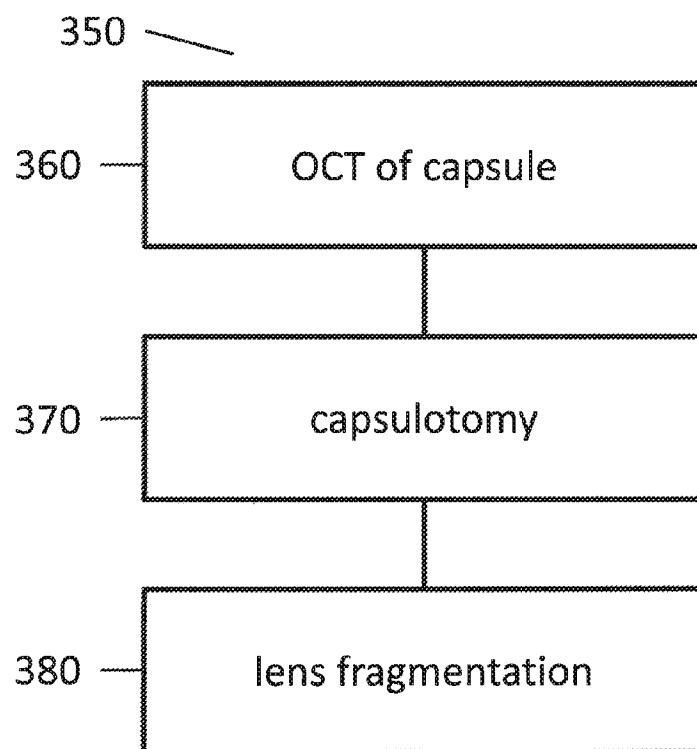


FIG. 8B

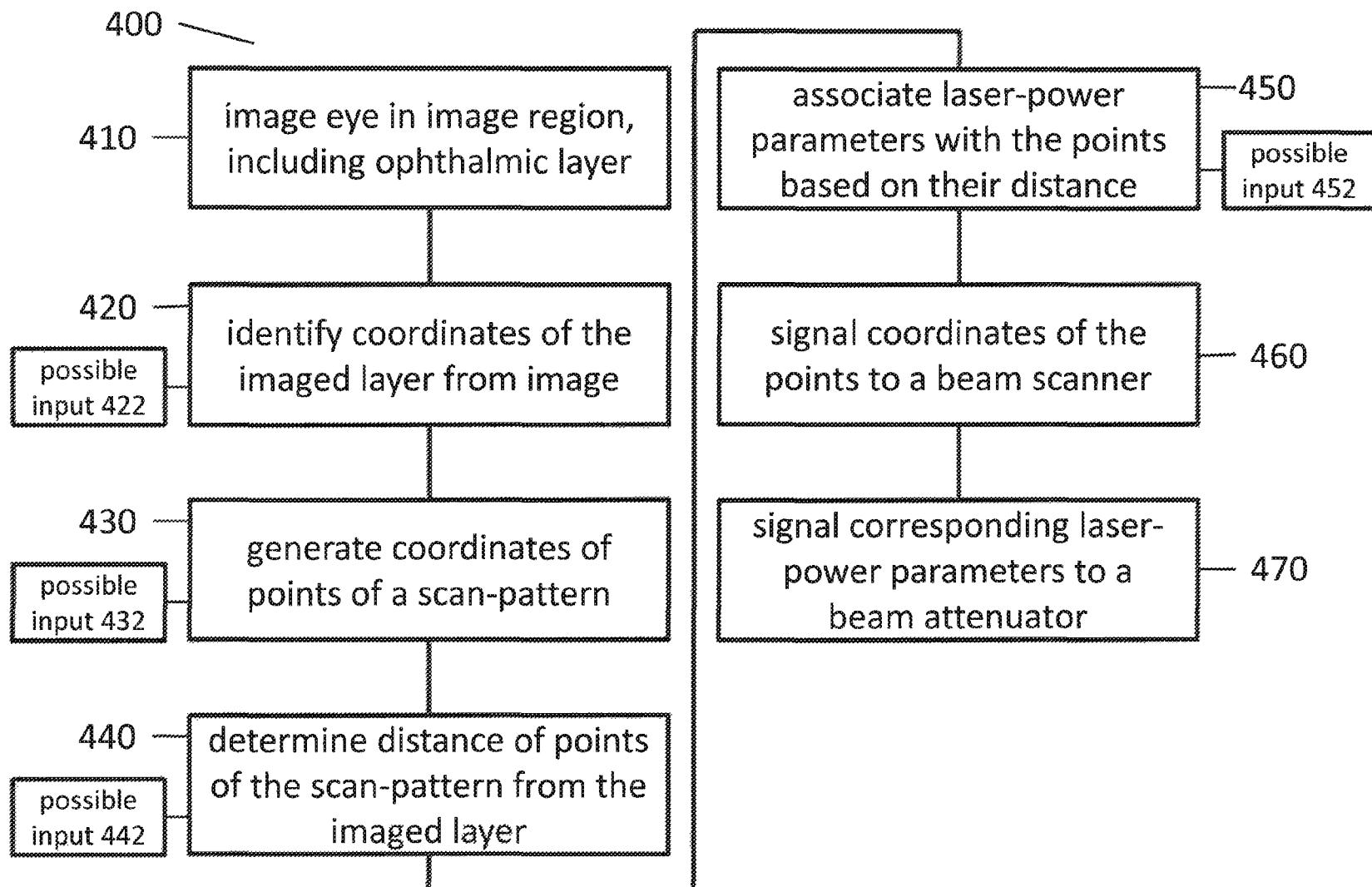


FIG. 9

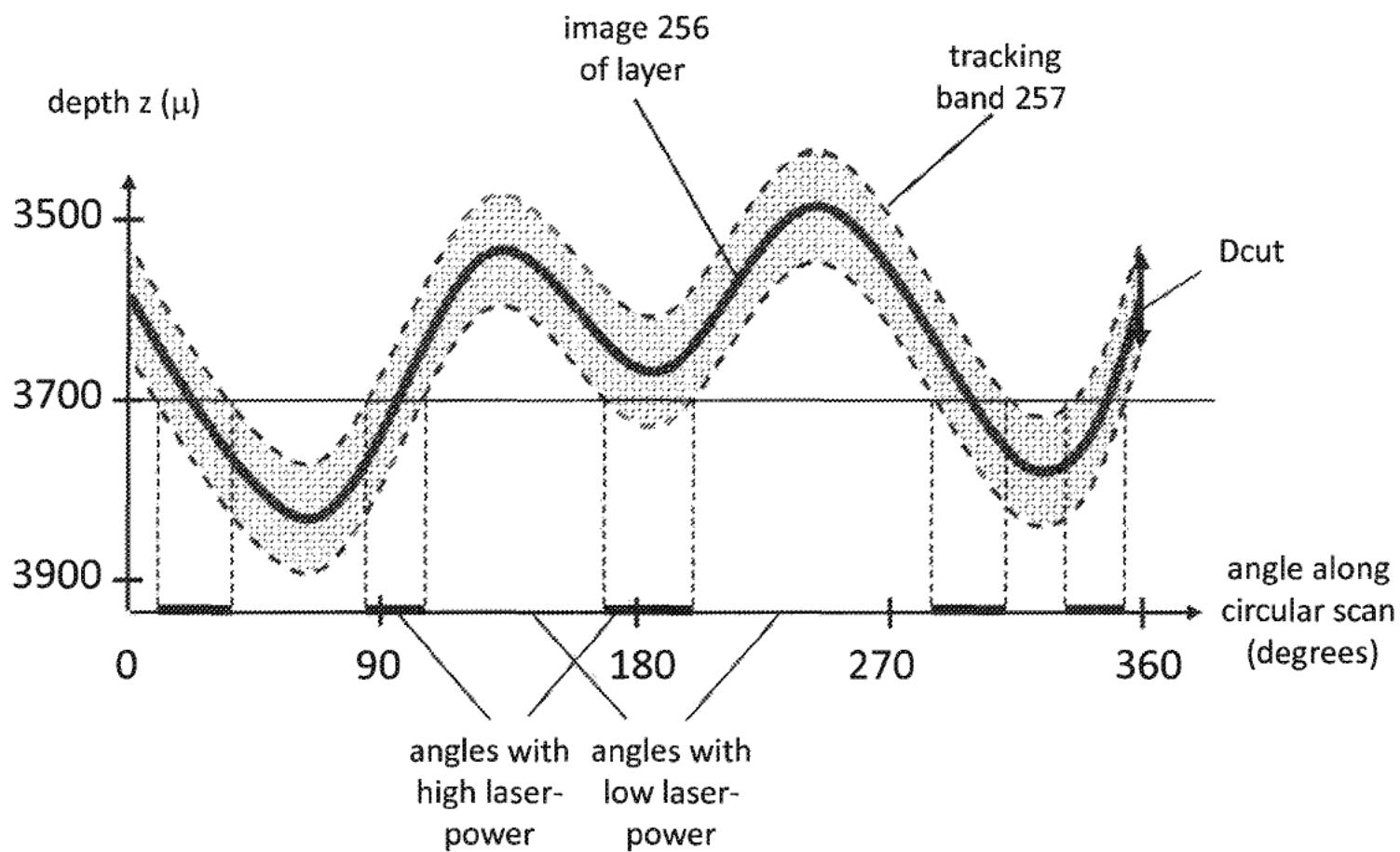


FIG. 10

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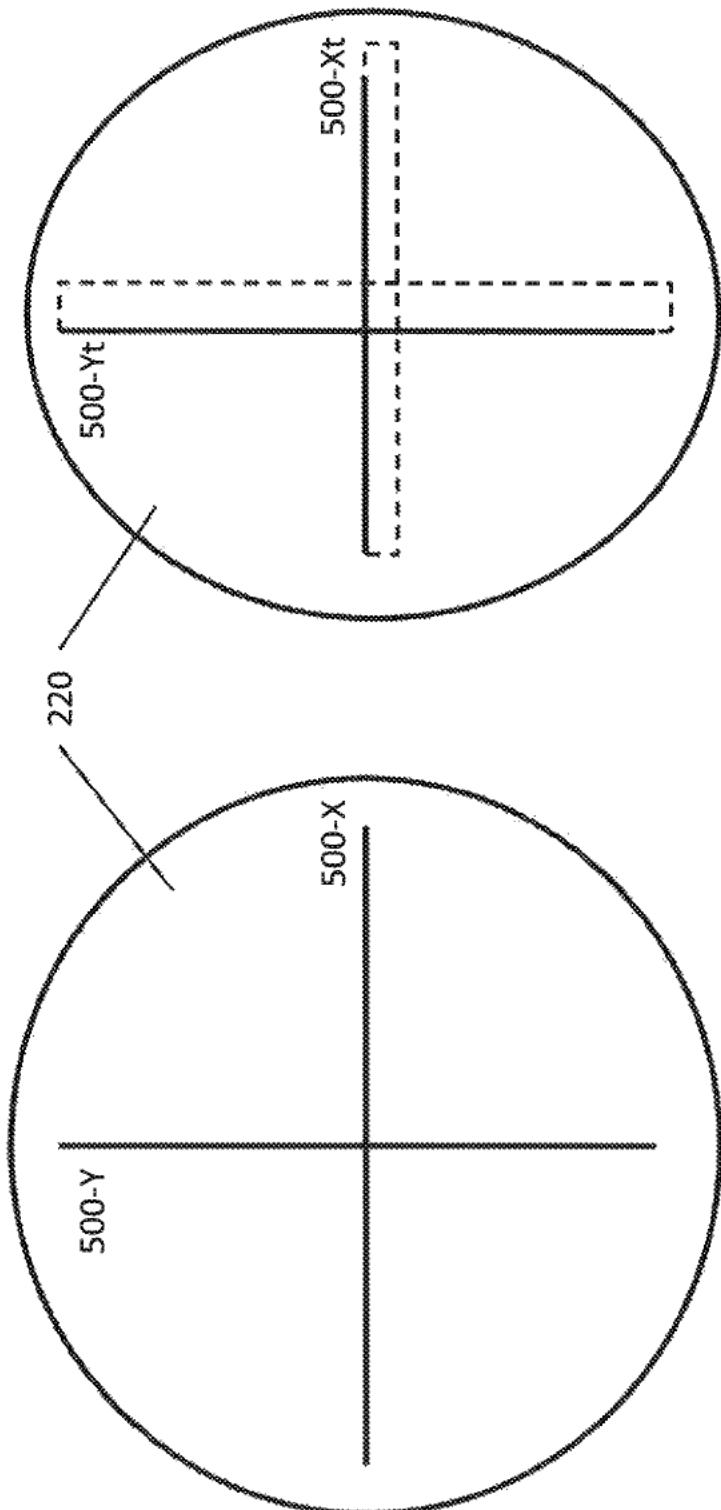


FIG. 11B

FIG. 11A

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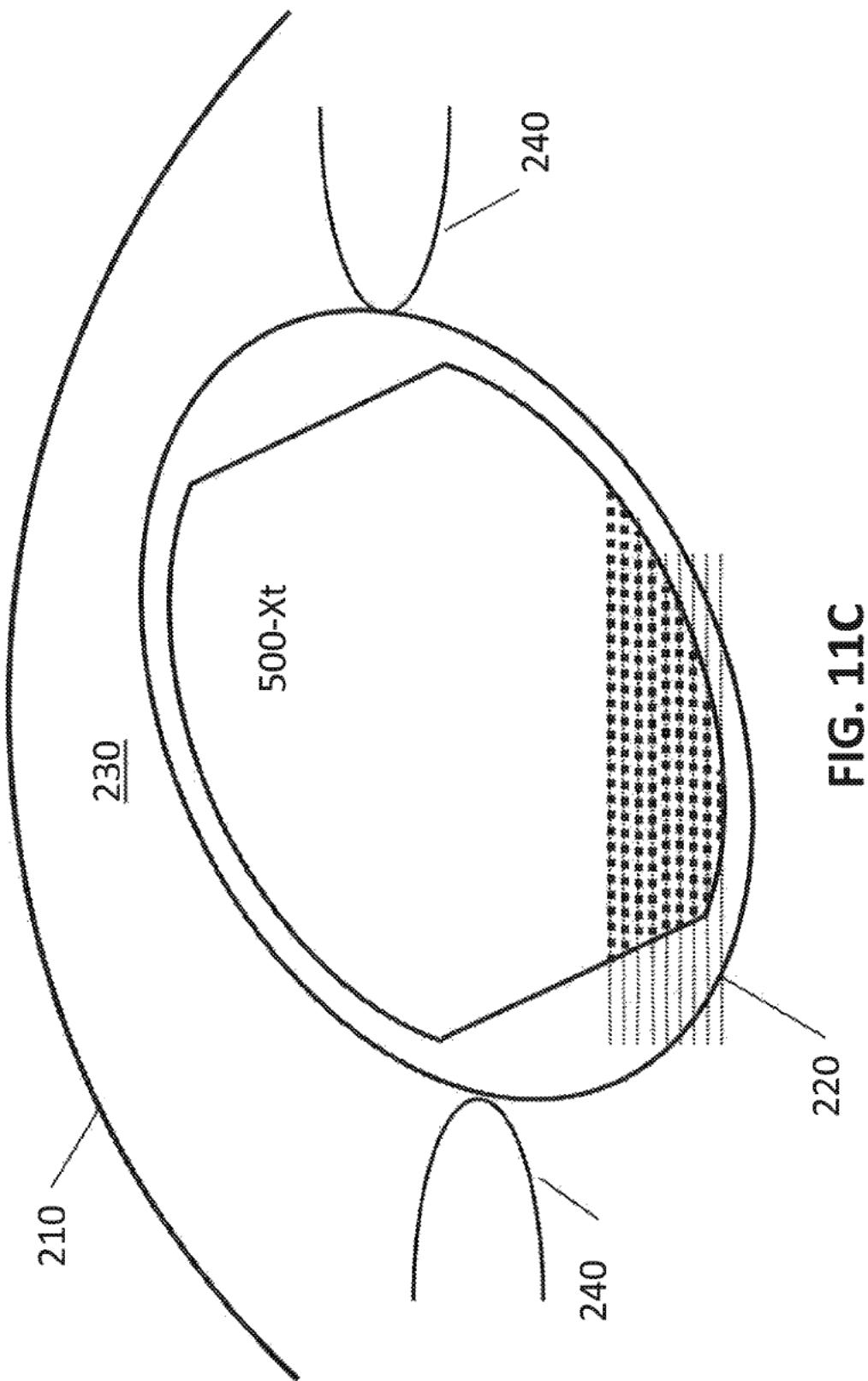


FIG. 11C

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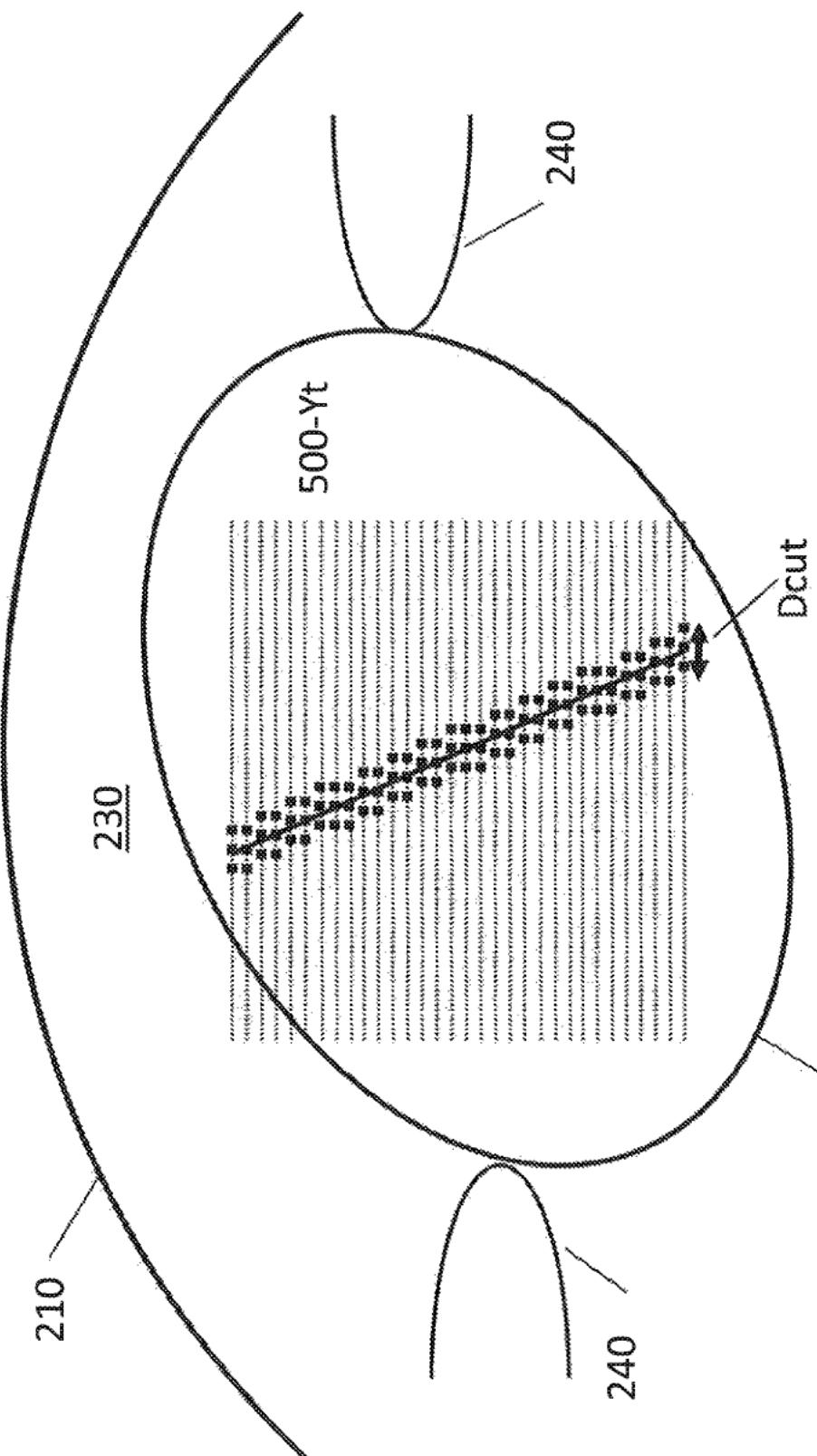


FIG. 11D

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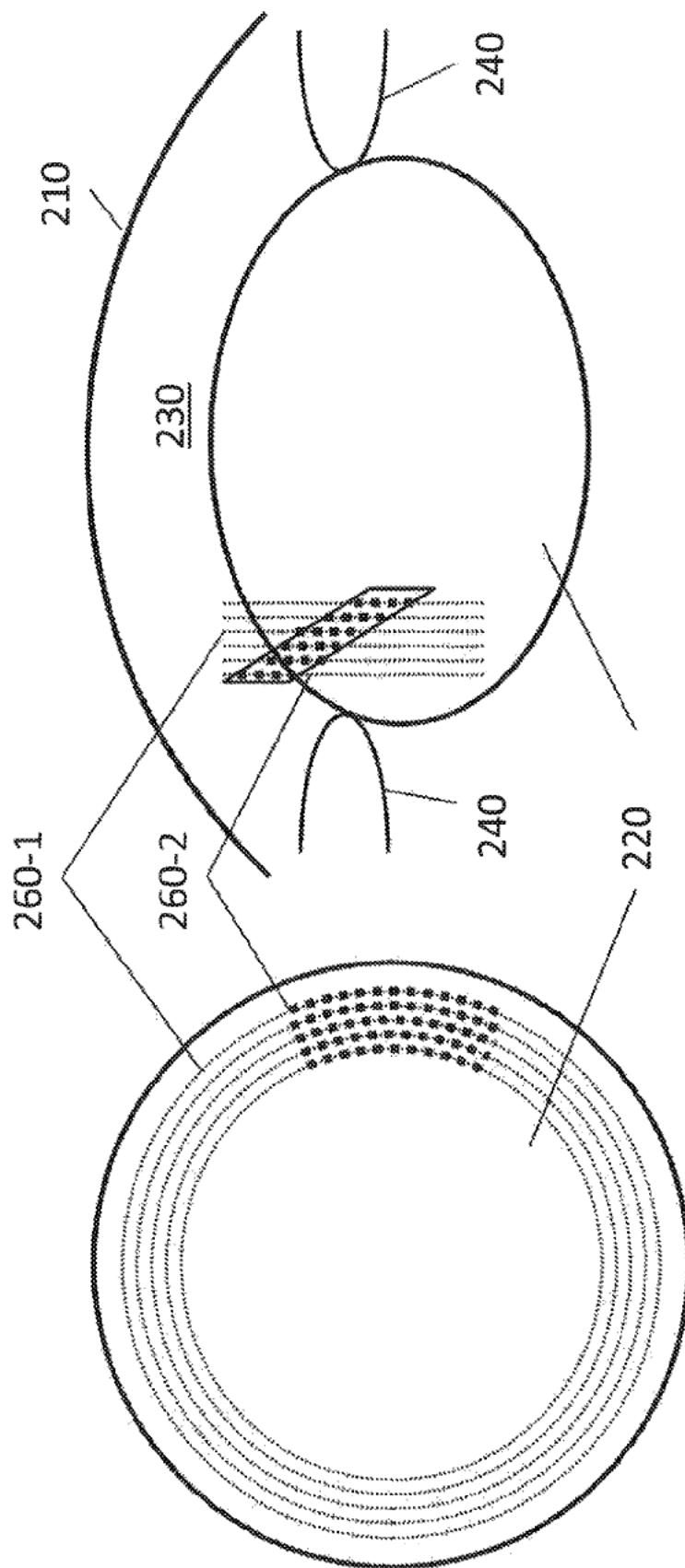


FIG. 12A
FIG. 12B

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IMAGING-CONTROLLED LASER
SURGICAL SYSTEM

TECHNICAL FIELD

This patent document describes a system and method for controlling a laser in an ophthalmic procedure. In more detail, this patent document describes an imaging-controlled laser system for controlling the power of a pulsed ophthalmic laser during capsulotomy and cataract procedures, among others.

BACKGROUND

Laser systems have become essential for ophthalmic surgery. They have been employed in corneal procedures for some time now with high precision and therefore considerable success. In very recent times applications for other ophthalmic procedures have been contemplated, including cataract procedures.

Lasers can be used for forming high precision cuts. These cuts are created by focusing or directing a rapid sequence of laser pulses to a scan-pattern or point-pattern. The points of the scan-pattern often form a line or layer and the laser pulses are directed to these points by a scanning system that includes deflection devices, mirrors and lenses whose alignment can be changed very quickly. In typical laser systems the pulses can have a duration or pulse length in the nanosecond, picosecond, or even femtosecond range. The pulse repetition rate can be in the kHz to hundreds of kHz range.

The power or energy of the laser pulses can be chosen to exceed a so-called photodisruption threshold. Laser pulses with a power above this threshold can disrupt the ophthalmic tissue at the target points, inducing the formation of bubbles. Lines or layers of these bubbles can weaken the mechanical connection between the tissue-portions on the opposite sides of the bubbles. Often the weakening is substantial, effectively cutting the tissue. Therefore, a subsequent manual procedure can completely separate the tissue portions with ease.

One ophthalmic procedure which could benefit from using such a high precision laser cutting system is cataract surgery. A typical cataract surgery involves a capsulotomy step and a lysis or lens fragmentation step. During lysis, energy is applied to a lens nucleus to liquefy it. During lens fragmentation, or phaco-fragmentation, the nucleus of the lens can be cut into several pieces by scanning the laser along cutting surfaces to enable the subsequent piece-by-piece removal of the nucleus. The capsulotomy involves forming a circular cut on the anterior portion of the capsular bag of the lens to allow the surgeon to access and remove the cut-up pieces of the nucleus.

To optimize surgical laser systems for these complex ophthalmic procedures is a great challenge. However, the optimization promises great returns in terms of the precision and efficacy of the surgical procedures.

SUMMARY

One of the challenges of laser cataract surgery is that the procedures of capsulotomy and lens fragmentation can interfere with each other. In advanced laser systems the precision of the surgery can be enhanced by imaging the ophthalmic target tissue prior to the surgery and guide the laser pulses based on the image. If the lens fragmentation is performed first, then, as a surgical by-product, the capsule is expanded

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considerably and unevenly by the substantial amount of bubbles formed inside the capsule. Therefore, after the lens fragmentation, the capsule and lens has to be imaged for a second time to guide the subsequent circular cut of the capsulotomy. However, imaging the severely photodisrupted and distorted lens can be challenging. Also, the repeated imaging procedure consumes precious surgical time, increasing the discomfort of the patient, potentially undermining the precision of the entire procedure.

On the other hand, if the capsulotomy is performed first, it creates a substantial amount of bubbles in the anterior region of the lens and in the anterior aqueous chamber of the eye. The amount of bubbles is especially high if the lens is in a tilted position before the procedure, as explained below.

These bubbles can increase the scattering of the laser pulses of the subsequent lens fragmentation considerably as the subsequent pulses are directed to the inside of the lens and thus propagate through the bubble-rich anterior region. The increased scattering can again potentially undermine the precision of the cataract procedure.

Thus, both sequences of the lens fragmentation and capsulotomy have drawbacks, as the first step can reduce the precision and control of the subsequent step. Therefore, laser systems that reduce, resolve, or eliminate one or more of these drawbacks can offer advantages.

Embodiments of the present invention can provide advantageous functionalities in view of these challenges. In particular, an embodiment of an imaging-based laser system can include a laser-beam system, configured to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye, and an imaging-based laser-controller, configured to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

An implementation of an imaging-based laser system can include a laser that generates and directs a beam of laser pulses into an eye, an imaging system that images a capsule layer of the eye, and a laser control system that controls the laser to direct the beam to spots within a tracking band of the imaged capsule layer with a laser-power parameter above a photo-disruption threshold, and to spots outside the tracking band of the imaged capsule layer with a laser-power parameter below a photo-disruption threshold, wherein the image-based laser system is configured to perform a capsulotomy before a lysis or lens- or phaco-fragmentation during a cataract procedure.

An implementation of an image-guided ophthalmic laser system can include a laser engine, configured to generate laser pulses, a beam modifier, configured to modify a laser-power parameter of the laser pulses, a laser scanner, configured to direct the laser pulses to scanning-points in an eye, an imaging system, configured to image a region in the eye, and a pattern generator, coupled to the imaging system, the beam modifier and the laser scanner, configured to generate coordinates of the scanning-points for the laser scanner, and to associate a laser-power parameter with the scanning-points depending on a distance of the scanning-points from a target-pattern.

In some implementations, a method of performing an imaging-controlled ophthalmic procedure can include imaging a layer in an eye, generating coordinates of points of a scan-pattern, determining a distance of the points of the scan-pattern from the imaged layer, and associating laser-power parameters with the points based on the determined distance.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an embodiment of a surgical laser system with an imaging-controlled laser system

FIGS. 2A-D illustrate embodiments of the laser-beam system.

FIGS. 3A-E illustrate embodiments of the imaging-based laser controller.

FIGS. 4A-B illustrate the scan-patterns for non-tilted and tilted lenses.

FIGS. 5A-B illustrate traditional scan-patterns for non-tilted and tilted lenses as a function of a scanning variable.

FIGS. 6A-H illustrate a scan-pattern along a circular scan with a distance-dependent laser-power parameter.

FIG. 7 illustrates a determination of the z-depth of the imaged layer by using a model curve.

FIG. 8A-B illustrate methods of cataract surgery with the lens fragmentation and capsulotomy in different sequences.

FIG. 9 illustrates a method of cataract surgery with an imaging-controlled laser system in detail.

FIG. 10 illustrates a multi-extrema tracking-band laser scan-pattern after lens-fragmentation expanded the lens capsule in a non-uniform manner.

FIGS. 11A-D illustrate scan-patterns for tilted chop cuts.

FIGS. 12A-B illustrate scan-patterns for tilted volume cuts.

DETAILED DESCRIPTION

Implementations and embodiments described in this patent document offer improvements for the above described challenges.

FIG. 1 illustrates an imaging-based laser system 100, including a laser-beam system 110 to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye 1, and an imaging-based laser-controller 120 to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer. The laser-controller 120 can perform these functions by sending a power control signal and a scanning control signal to the laser-beam system 110, for example.

The laser beam of the laser-beam system 110 can be guided into the main optical pathway at a beam-splitter 132-1 that can redirect the beam to an objective 134. The beam can propagate through the objective 134 and through a patient interface 136 to enter into the surgical eye 1.

The surgery can be assisted by imaging the eye 1 with various techniques. A visible imaging light can be used to create a video image that is processed by a video microscope 138. In addition, the imaging-based laser-controller 120 can shine an imaging beam on the eye and form an image based on the returned image beam. This imaging beam can be coupled into and out of the main optical path by a beam-splitter 132-2.

FIGS. 2A-D illustrate various embodiments of the laser-beam system 110.

FIG. 2A illustrates that embodiments of the laser-beam system 110 can include a laser engine 112 to generate the beam of laser pulses, a beam attenuator 114 to modify the laser-power parameter of the laser pulses, and a beam scanner 116 to direct the beam of laser pulses to the points of the scan-pattern in the eye. The laser engine 112 can generate laser pulses with a duration of nanoseconds, picoseconds or even femtoseconds, i.e. in the 10^{-9} - 10^{-15} sec

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range. These pulses can be generated at a repetition rate in a wide range of frequencies: from 0.1 kHz to 1,000 kHz, or in a range of 1 kHz to 500 kHz, or in some implementations in the 10 kHz to 100 kHz range. The power control signal of the laser-controller 120 can be coupled into the beam attenuator 114 and the scanning control signal of the laser-controller 120 can be coupled into the beam scanner 116.

The beam attenuator 114 can include a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, or an energy wheel. Each of these implementations can modify a laser-power parameter of the laser pulses. The laser-power parameter can be a pulse energy, a pulse power, a pulse length or a pulse repetition rate of the laser pulses, among others. The beam attenuator 114 can modify one or more of these laser-power parameters. In a simple implementation, the beam attenuator 114 can shutter or block selected laser pulses. In another, a polarizer assembly can reduce the power of selected laser pulses by adjusting the relative angle of subsequent polarizing filters.

In the embodiment of FIG. 2A, the beam attenuator 114 can be located between the laser engine 112 and the beam scanner 116 in the path of the laser beam.

FIG. 2B illustrates and embodiment in which the beam attenuator 114 is at least partially integrated into the laser engine 112. In some cases, the beam attenuator 114 can be part of the laser engine 112. For example, a Pockels cell within the laser engine 112 can be the beam attenuator 114.

FIG. 2C illustrates and embodiment in which the beam attenuator 114 is located after the beam scanner 116 in the path of the laser beam.

Finally, FIG. 2D illustrates an embodiment in which the beam attenuator 114 and the beam scanner 116 are at least partially integrated.

FIGS. 3A-E illustrate various embodiments of the imaging-based laser-controller 120.

FIG. 3A illustrates that the laser-controller 120 can include an imaging system 122 to image the imaged layer in the eye and a pattern generator 124 to generate coordinates of the points of the scan-pattern, to associate laser-power parameters with the points depending on the distance of the points from the imaged layer, and to signal the generated coordinates of the points and the corresponding laser-power parameters to the laser-beam system 110. In some implementations, the imaging system 122 can image any ophthalmic target in the anterior or posterior segment of the eye, targets from the cornea to the retina.

The pattern generator 124 can signal the generated coordinates of the points of the scan-pattern to the beam scanner 116 with a scanning control signal. Further, the pattern generator 124 can signal the laser-power parameters corresponding to the points of the scan-pattern to the beam attenuator 114 with a power control signal. The laser-power parameter can be a pulse energy, a pulse power, a pulse length or a pulse repetition rate of the laser pulses.

The imaging system 122 can include an ophthalmic coherence tomography (OCT) system, a Scheimpflug imaging system, a scanning imaging system, a single shot imaging system, an ultrasound imaging system, and a video imaging system. Here, the scanning imaging systems can create the image by scanning an imaging beam, whereas single shot imaging systems can acquire imaging information about an imaged area or volume in a single shot. The OCT system can be a time-domain OCT, a frequency-domain OCT, or a spectrometer-based OCT system, among others.

FIG. 3B illustrates that in some implementations the laser-controller 120 can include an image-analyzer 126. The

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image analyzer 126 can receive the image of the imaged layer from the imaging system 122, perform an analysis of the imaged layer as described below and forward the result of the analysis to the pattern generator 124.

FIG. 3C illustrates that in some implementations the image analyzer 126 can be at least partially integrated with the imaging system 122. FIG. 3D illustrates that in some implementations the image analyzer 126 can be at least partially integrated with the pattern generator 124.

FIG. 3E illustrates that in some embodiments, the laser system 100 can include an operator-interface 128 that can be coupled to one or more of the imaging system 122, the pattern generator 124 and the image analyzer 126.

FIGS. 4A-B set the stage to illustrate the operation of the laser system 100. The imaging system 122 can image the imaged layer in an image region that can be based on a loop, an arc, a line, or a two-dimensional pattern transverse to a z-axis of the imaging system, and extends to a depth range Dimage along the z-axis of the imaging system. The imaging system 122 can support a determination of a z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image-scan.

FIG. 4A illustrates that the imaging system 122 can perform an imaging relevant for a capsulotomy step of a cataract procedure. The schematic cross section illustrates the anterior segment of the eye 1. The outermost layer is a cornea 210. A crystalline lens 220 is located behind the cornea 210, separated from it by an aqueous anterior chamber 230. The crystalline lens 220 is encapsulated in a thin capsule or capsular bag 222. The lens 220 is held in place by ciliary muscles 240. These muscles 240 also adjust the shape of the crystalline lens 220 as needed for bringing objects into focus.

As it has been described above, in order to facilitate the removal of a fragmented nucleus of the lens 220, the cataract surgery typically involves creating a circular capsulotomy cut 250 on the capsular bag 222. As a first step, the imaging system 122 can create an image 252 of the anterior segment of the eye by scanning along a scanning circle 254 and imaging the eye in a depth-range Dimage, defining an image-cylinder 260-i.

FIG. 5A illustrates that the image 252 typically includes an image 256 of the imaged anterior capsule layer of the lens 220 “unfolded” along a scanning variable, such as an angle along the circumference of the scanning circle 254. If a z-axis of the lens 220 is aligned with a z-axis of the laser system 100, the image 256 of the imaged layer is a flat line, indicating an essentially constant z-depth.

In other implementations, the image 252 can include the image of other ophthalmic targets, including corneal layers, portions of the sclera and even retinal layers. The zero depth level can be defined in a large number of ways, using a lens of the objective 134, a reference mirror of the imaging system 122, a level of the patient interface 136, or a level of an ophthalmic structure, such as the cornea 210.

By analyzing the image 252, a surgeon can recognize the image 256 of the imaged layer. Based on the z-depth of the imaged layer, the surgeon can decide where to direct the cutting laser beam to form the capsulotomy cut 250. The cutting laser beam is typically scanned along the same scanning circle 254 to form a cut-cylinder 260-c with a depth-range Dcut, typically smaller than Dimage. This way the placement of the cut-cylinder 260-c benefits maximally from the information contained in the image 252, and in particular in the image 256 of the imaged layer. The capsulotomy cut 250 is formed where the cut-cylinder 260-c intersects the lens capsule 222. In practice, the cut cylinder

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260-c is often formed as a stack of bubble-circles, where the individual circles are created by directing the laser pulses along a circular scan-pattern at a fixed z-depth to cause photodisruption, followed by the formation of a similar circle at a slightly lesser z-depth.

In some typical cases, the image depth-range Dimage can be 5-10 millimeters, whereas the cut depth-range Dcut can be in the range of 50-200 microns, in some cases 75-150 microns, sometimes approximately 100 microns.

It is noted that the bubbles of the cut-cylinder 260-c can scatter and deflect laser pulses applied in subsequent surgical steps. For example, in a cataract surgery the capsulotomy can be followed by the lens fragmentation or lysis. The bubbles of the cut-cylinder 260-c can negatively impact the precision and efficiency of this subsequent lens-fragmentation by scattering the lens-fragmenting laser pulses.

Fortunately, when a z-axis of the lens 220 is parallel to a z-axis of the laser system 100, the depth range Dcut of the cut cylinder 260-c can be as little as 100 microns, creating only a limited number of bubbles. Thus, in the case of a well-aligned lens 220, the bubbles of the cut-cylinder 260-c introduce only a limited amount of scatter for the subsequent lens fragmentation laser pulses.

FIG. 4B illustrates, however, that in the typical surgical case the crystalline lens 220 can be tilted. This situation can occur for a variety of reasons. For example, the weight of the objective 134 can push the lens 220 sideways upon docking to the eye 1. Or, applying suction at the patient interface 136 to immobilize the eye 1 can lead to a tilting of the lens 220 as well.

FIG. 5B illustrates the image 252 of such a tilted lens 220 unfolded along the angular scanning variable of the scanning circle 254. In contrast to the non-tilted case of FIG. 5A, the image 256 of the tilted imaged layer can exhibit substantial sinusoidal oscillations. The amplitude of these oscillations can be as much as 300-500 microns. To make sure that the capsular bag 222 is cut everywhere along this sinusoid, the cut-cylinder 260-c can be formed with a much enlarged depth-range Dcut, exceeding the amplitude of the sinusoid. In the above example, Dcut can be 400-600 microns to be sure that the capsular bag 222 was cut along the entire sinusoid. Clearly, this approach may create 4-6 times more photodisrupted bubbles during capsulotomy than the procedure for a non-tilted lens. Capsulotomy bubbles in such an increased number can scatter the laser pulses of the subsequent lens fragmentation to a substantial degree, threatening its precision and efficacy.

FIGS. 6A-H illustrate that some implementations of the laser system 100 can substantially reduce the number of photodisrupted bubbles by generating bubbles only in a narrow proximity of the imaged layer.

As described above, this outcome can be achieved, for example, by the imaging-based laser-controller 120 imaging the capsular bag 222, controlling the scanning of the beam of laser pulses to the points of the scan-pattern, and controlling a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

FIGS. 6A-B illustrate that as the laser pulses are directed to points of the scan-pattern, the laser controller 120 can modify or adjust a laser-power parameter of the pulses. In particular, when a laser pulse is directed to a point of the scan pattern that is within a Dcut distance from the image 256 of the imaged layer along the z axis, the laser-controller 120 can adjust its laser-power parameter to a high value, e.g. above a photodisruption threshold. Whereas, when a laser pulse is directed to a point of the scan pattern that is farther

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than Dcut from the image 256 of the imaged layer, the laser-controller 120 can adjust its laser-power parameter value to a low value, such as below a photodisruption threshold.

The just-described method creates bubbles only in a Dcut proximity of the imaged layer and therefore substantially reduces the number of bubbles to a value close to the number of bubbles for a well-aligned lens. For this reason, the scattering of the subsequent lens-fragmenting laser pulses by these capsulotomy bubbles is substantially reduced. Using the earlier value of Dcut being 400-600 microns for a tilted lens and 100 microns for a non-tilted lens, the present method may reduce the scattering of the lens-fragmenting bubbles by a factor of 4-6: a considerable gain in precision and control.

FIG. 6A illustrates the implementation when the scanning of the capsulotomy laser pulses of the scan-pattern is performed along the z-axis for fixed points of the circular scan. FIG. 6B illustrates the implementation when the scanning is performed along the circular scan with a fixed z-depth. This implementation can be used to create the above mentioned stacked circles. In either implementation, the points with high laser-power are placed within a tracking band 257 with a z-extent of Dcut.

FIGS. 6C-E illustrate the implementation when the laser pulses are scanned at fixed z-depths along the circular scan. A tracking band 257 can be defined as the set of points of the scan-pattern that are within the preselected distance Dcut from the image 256 of the imaged layer.

FIGS. 6D-E illustrate the laser power parameter of the pulses along the circular scan at two selected z-depths of 3600 microns and 3650 microns in an unfolded representation. The laser-controller 120 can control the laser power of the pulses that are directed to points inside the tracking band 257 to be above a photo-disruption threshold, and the laser power of the pulses that are directed to points outside the tracking band 257 to be below the photo-disruption threshold. In this embodiment, photodisrupted bubbles are only generated at points within the tracking band 257, achieving the above functionality of the laser system 100.

FIG. 6F expresses the same operation in a folded representation. Here the value of the laser power parameter is shown as a function of the angular scanning variable (typically the angle), projected on the scanning circle 254 itself. Again, for those points of the scan-pattern that lie within the tracking band 257, the laser power is high—indicated by a thick line—whereas for those points that lie outside the tracking band 257, the laser power is low.

FIGS. 6G-H illustrate a related implementation, where the laser-power controller 120 controls the laser power parameter as a function of the distance of the points from the imaged layer, wherein the laser-power is a decreasing function of the distance. FIG. 6G illustrates the implementation where this function is essentially a two-valued step-function. FIG. 6H illustrates the implementation where this function is a continuous function, its value decaying with the increasing distance from the imaged layer. In some implementations, it may be easier to control the laser power in the continuous manner of FIG. 6H.

The above-outlined implementations depend on the knowledge of the distance between the points of the scan-pattern and the imaged layer. Three stages are involved in determining this distance. First, the identity of the imaged layer is identified in the image 252 to determine the image 256 of the imaged layer. Then, the z-depth coordinate of the imaged layer is determined. Finally, the distance of the imaged layer and the points of the scan-pattern can be

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determined, for example, by taking the difference of the z-depth coordinates of the points of the scan-pattern and the imaged layer at the corresponding angular scanning coordinates, such as at the same angle.

Concerning the first step, the raw image 252 does not isolate or identify the imaged layer explicitly. Thus, establishing the identity of the imaged layer may necessitate an analysis of the image 252. As discussed earlier, this analysis of the image can be performed by the imaging system 122, the pattern generator 124, or the image analyzer 126, possibly assisted by an input from a system operator through the operator interface 128.

FIG. 7 illustrates that the imaging system 122 can support the identification of the imaged layer and the determination of its z-depth coordinates in different ways. In some implementations the laser system 100 can include the operator interface 128 and the imaging system 122 can support the identification of the imaged layer using an input from an operator through the operator interface 128.

For example, on a graphical user interface, or GUI, the operator interface 128 can prompt the operator to fit a model curve 258 to the spots in the image 252 representing the imaged layer. Since in the case of a tilted ellipsoid-shaped lens the image 256 of the imaged layer is typically a sinusoidal curve, the operator interface 128 can display a generic sinusoidal curve 258 on the GUI and prompt the operator to fit this model curve 258 to the layer-spots in the image 252. Once the operator fitted the model curve 258 to the layer-spots in the image 252, the model curve 258 can serve as the image 256 of the imaged layer.

The operator can achieve this task through various approaches: by shifting the model curve 258 by an Xshift in the X direction (i.e. adjusting the angle along the circular scan) and by shifting the model curve 258 by a Yshift in the Y direction (i.e. adjusting the z-depth coordinate). In other implementations the operator can be prompted to adjust the scale of the model curve 258 to the scale of the sinusoidally located layer-spots in the image 252, i.e. to rescale the z-depth of the model curve 258 to fit the z-depth of the layer-spots. Many other fitting techniques can be implemented to achieve analogous functionalities.

The operator interface 128 can receive the input from the operator in many different ways, including through a keyboard, a touch-screen, a computer-communication channel, an external memory, a flash-drive, an internet connection, a speech-recognition apparatus or a wireless connection.

In other implementations, the determination of the identity and the z-depth of the imaged layer can be performed by the laser system 100 without the input of a surgeon or operator. In particular, the imaging system 122 can be configured to determine the identity and then the z-depth coordinate of the imaged layer by a processor or micro-computer performing a feature-recognition analysis of the image 252. For example, the imaging system 122 can determine the identity and coordinates of the imaged layer by locating local maxima of the gradient of the spot intensity. In other implementations, an edge-recognition algorithm can be used. In these implementations, the imaging system 122 can identify the manifold of the maximum-gradient points as the image 256 of the imaged layer without resorting to fitting a model curve 258. In some implementations, of course, the imaging system 122 can make use of a model curve 258 to identify the image 256 of the imaged layer.

In the above implementations, once the identity of the imaged layer has been determined in the image 252, the z-depth coordinates of the imaged layer can be determined

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in a straightforward manner, for example, by counting the pixels in the image 252, or using a reference or a look-up table.

For the image analysis, the imaging system 122 can utilize a result of a pre-surgery measurement, statistical data, video image data, ophthalmic coherence tomography image data, or a model-based computation during the determination of the z-depth.

Once the z-depth of the imaged layer has been determined, the imaging system 122 can forward the z-depth and the corresponding scanning coordinates of the imaged layer to the pattern generator 124 to carry out the last stage, the determination of the distance between the imaged layer and the points of the scan-pattern, generated by the pattern generator 124. This stage can be carried out, for example, by subtracting the z-depth coordinates of the points of the scan-pattern from the z-depth coordinates of the imaged layer that correspond to the same scanning variable, such as the same scanning angle.

Finally, having determined the distance of the points of the scan-pattern from the imaged layer, the pattern generator 124 can associate a laser-power parameter above a photodisruption threshold with those points that are closer to the imaged layer than a predetermined distance, and associate a laser-power parameter below a photodisruption threshold with those points that are farther from the imaged layer than the predetermined distance, as described in relation to FIGS. 6A-H.

In some implementations, the imaging system 122 only captures the image 252 but does not identify the imaged layer or determine its z-depth coordinates. In these embodiments, the imaging system 122 can simply forward the unprocessed image 252 to the pattern generator 124 without analyzing it. The pattern generator 124 can receive the image 252, identify the imaged layer and determine the z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image scan.

As above, in some implementations, the pattern generator 124 can determine the z-depth of the imaged layer by performing a feature-recognition analysis of the received image 252. In other implementations, the pattern generator 124 can receive an operator input through the operator interface 128 during the process of determining the z-depth of the imaged layer, as described before.

In these implementations, once the z-depth coordinates of the imaged layer have been determined, the pattern generator 124 can define a tracking band 257 as a manifold of the points of the scan-pattern that are within a predefined distance from the coordinates of the imaged layer. Then the pattern generator 124 can associate a laser-power parameter above a photodisruption threshold with points of the scan-pattern inside the tracking band 257, and a laser-power parameter below a photodisruption threshold with points of the scan-pattern outside the tracking band 257.

Yet other implementations of the laser controller 120 may include an image analyzer 126 that can determine the z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image-scan. As was illustrated in FIGS. 3B-D, the image analyzer 126 can be self-standing or at least partially integrated with the imaging system 122 or the pattern generator 124.

The image analyzer 126 can identify the imaged layer and determine the z-depth coordinate of the imaged layer by performing a feature-recognition analysis of the image 252. In other implementations, the image analyzer 126 can determine the z-depth coordinate by making use of an operator input through an operator-interface 128.

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The operation of the laser system 100 can be demonstrated on the example of the capsulotomy procedure, where the imaged layer is the lens capsule 222 between the lens 220 and the aqueous anterior chamber 230. In this case, the scan-pattern corresponds to the cut-cylinder 260-c intersecting the lens capsule 222 at the capsulotomy cut 250. The pattern generator 124 can associate a photodisruptive laser-power parameter with points inside a tracking band 257 related to the intersection 250 of the cut-cylinder 260-c and the lens capsule 222, and a non-photodisruptive laser-power parameter with points outside the tracking band 257.

FIG. 8A illustrates a first cataract procedure 300 performed without the benefits of the laser system 100. The cataract procedure 300 can be practiced when the capsulotomy generates an excessive number of bubbles as in FIGS. 4B-5B. To prevent excessive scattering by these capsulotomy bubbles, the lens fragmentation is performed prior to the capsulotomy. In detail, the cataract procedure 300 can include a first imaging 310 of the capsule 222, performed by an OCT procedure, followed by a lens fragmentation 320. During the lens fragmentation 320 the capsule 222 expands because of the large number of bubbles generated in the crystalline lens 220. The fragments of the lens 220 are removed through an opening, cut into the capsule 222 by a capsulotomy 340. However, since the capsule 222 has expanded during the lens fragmentation 320, the results of the first imaging 310 are not reliable anymore. Therefore, the capsulotomy 340 has to be preceded by a second imaging 330. The second imaging 330 can take up precious surgical time and increase the discomfort of the patient. Both of these factors can endanger the efficacy of the cataract procedure 300.

FIG. 8B illustrates a cataract procedure 350 with an embodiment of the laser system 100. Since the laser system 100 is capable of creating only a limited number of bubbles during the capsulotomy, the capsulotomy can be performed before the lens fragmentation. This change of sequence can reduce the surgical time to a considerable degree and thus increase the precision of the cataract procedure substantially.

In some detail, the cataract procedure 350 can include an imaging 360 of the capsule 222, e.g. by an OCT imaging system, followed by a capsulotomy 370, and completed by a lens fragmentation 380. Since the capsulotomy 370 does not deform the lens 220, there is no need for a second imaging, in contrast to the procedure 300.

FIG. 9 illustrates an imaging-controlled cataract method 400 in more detail. The method 400 can include an imaging 410 of an imaged ophthalmic layer in an imaged region of an eye, followed by an identifying 420 of the coordinates of the imaged layer from the image. These tasks can be performed, for example, by the imaging system 122 of the imaging-based laser-controller 120. The identifying 420 can include performing a feature-recognition analysis. In other cases, it can include receiving an operator-input through an operator interface 128. These tasks can be performed by the imaging system 122, the pattern generator 124 or the image analyzer 126.

Next, the method 400 can include a generating 430 of coordinates of points of a scan-pattern, and a determining 440 of a distance of the points of the scan-pattern from the imaged layer. These steps can be performed for example, by the pattern generator 124.

The method 400 can further include an associating 450 of laser-power parameters with the generated points based on their determined distance. The tasks 420 to 450 can include receiving possible inputs 422-452 from an operator of the laser system 100 through the operator interface 128.

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The method can also include a signaling 460 of the generated coordinates of the points of the scan-pattern to the beam scanner 116 and a signaling 470 of the corresponding laser-power parameters to the beam attenuator 114.

FIG. 10 illustrates the case of surgical relevance when the lens capsule 222 has an uneven shape. This situation can arise in different circumstances. For example, the docking of the patient interface 136 can cause considerable deformation of the anterior segment of the eye 1. Or an ophthalmic trauma or a prior lens fragmentation procedure can result in an uneven lens shape. In any of these circumstances, the laser system 100 can be capable of analyzing an image 256 of the imaged layer that exhibits more than two local extrema. Visibly, a simple sinusoidal model curve 258 is insufficient to identify the imaged layer and to determine its z-depth coordinate in this case. Therefore, embodiments of the imaging system 122, the pattern generator 124 or the image analyzer 126 can be capable of recognizing the imaged layer and determine its z-depth coordinate even in this more challenging case, for example, by using sophisticated feature-recognition software. Having determined and characterized the image 256 of the imaged layer can allow the pattern generator 124 to define the tracking band 257 to associate laser-power parameters with the spots of the scan-pattern accordingly.

FIGS. 11A-D illustrate that the imaging system 122 of the laser system 100 can image a region in the eye, the pattern generator 124 can generate coordinates of points of a scan-pattern for the beam scanner 116, and associate a laser-power parameter with the points of the scan-pattern depending on a distance of the points from a target-pattern.

An example for such a target pattern can be a chop pattern 500, including the chop-planes 500-X and 500-Y. Such chop patterns 500 can be used for lens fragmentation. FIG. 11A illustrates the case when the z-axis of the lens 220 is aligned with the z-axis of the laser system 100. In this case the chop-planes 500-X and 500-Y are also parallel to the z-axis of the laser system 100.

FIG. 11B illustrates that if the lens 220 is tilted relative to the z-axis of the laser system 100, as illustrated e.g. in FIG. 4B, then the chop planes 500-Xt and 500-Yt can be tilted as well. Since the scan-pattern often includes a first manifold of points at a first fixed z-depth, followed by a second manifold 45 at a slightly lesser z-depth, the scan-pattern of tilted chop-planes with laser systems that cannot adjust the power of the laser pulses would create cuts into the capsular bag 222, leading to massive surgical complications.

In contrast, embodiments of the laser system 100 can 50 associate laser-parameters depending on the distance of the points of the scan-pattern from the chop planes 500-Xt and 500-Yt.

FIGS. 11C-D illustrate the points of the scan-pattern with low and high laser power, generated by the pattern generator 55 124 to form the tilted 500-Xt and 500-Yt chop planes. Visibly, creating cuts by adjusting the power of the laser pulses depending on their proximity to the target-pattern can avoid cutting into the capsular bag—a major surgical advantage.

FIG. 11D illustrates clearly that, as it was the case of the tracking band 257, a photodisruptive laser-power parameter can be associated with scan-points that are closer to the target-pattern 500-Xt and 500-Yt than a predetermined distance Dcut, and a non-photodisruptive laser-power parameter with the scan-points that are farther from the target-pattern than the predetermined distance Dcut.

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In other implementations, the cutting surface can be a circular surface-segment, a spiral surface-segment, a corneal access cut and a limbal relaxing cut.

FIGS. 12A-B illustrate that in some cases the target pattern 260-2 can be a target volume with an axis tilted relative to an optical axis of the laser system 100. Here, the scan pattern includes cylindrical patterns 260-1, and the laser-power parameter of the points of this scan-pattern is adjusted to form a tilted volume cut 260-2. Such a utility can 10 be useful for correcting a refractive property of the lens 220, for example.

In some implementations, the pattern generator 124 can be configured to associate the laser-power parameters with the points of the scan-pattern depending additionally on a 15 distance of the points from an ophthalmic layer, imaged by the imaging system 122.

While this specification contains many specifics, these should not be construed as limitations on the scope of the invention or of what can be claimed, but rather as descriptions of features specific to particular embodiments. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features can be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination can be directed to a subcombination or variation of a subcombination.

We claim:

1. An imaging-based laser system, comprising:
a laser engine configured to generate a beam of laser pulses;

an imaging-based laser-controller configured to:
determine z-depths of a sequence of points in a scan-pattern that correspond to a layer of the eye imaged by an imaging system;

generate a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer;

cause a beam scanner to scan the beam of laser pulses to the points of the scan-pattern, and

cause a beam attenuator to control the laser-power parameter of the laser pulses such that a laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold.

2. The system of claim 1, wherein: the layer of the eye imaged by the imaging system is tilted relative to a z-axis of the incision to be made in the eye.

3. The system of claim 2, wherein the imaging system comprises a timedomain optical coherence tomography (OCT) system, a frequency-domain OCT system, or a spectrometer-based OCT system.

4. The system of claim 2, wherein the imaging-based laser-controller is configured to determine the z-depths of the sequence of points in the scan-pattern that correspond to the layer of the eye imaged by the imaging system by performing a feature-cognition analysis of an image of the imaged layer.

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5. The system of claim 2, wherein: the imaged layer is a lens capsule between a lens of the eye and an aqueous chamber of the eye; and the tracking band corresponds to an intended capsulotomy cut intersecting the lens capsule.

6. The system of claim 1, wherein the beam attenuator comprises at least one of a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, and an energy wheel.

7. A method, comprising:

generating an image, with an imaging system, of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye;

determining, with an imaging-based laser-controller, z-depths of a sequence of points in a scan-pattern that correspond to the image of the layer;

generating, with the imaging-based laser-controller, a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer;

directing, with the imaging-based laser-controller, a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band.

8. The method of claim 7, further comprising: associating a photodisruptive laser-power parameter with points in the scan pattern that are inside the tracking band; and associating a non-photodisruptive laser-power parameter with points in the scan pattern than are outside the tracking band.

9. The method of claim 7, wherein determining z-depths of the sequence of points in the scan pattern that correspond to the imaged layer in the eye comprises performing a feature-recognition analysis to identify the imaged layer.

10. The method of claim 9, comprising: generating coordinates of the imaged layer corresponding to the scan pattern and the tracking band; signaling the coordinates to a beam scanner; and signaling laser-power parameters to a beam attenuator.

11. The method of claim 10, wherein signaling laser-power parameters to a beam attenuator comprises: signaling a photodisruptive laser-power parameter associated with points in the scan pattern that are inside the tracking band; and signaling a non-photodisruptive laser-power parameter associated with points in the scan pattern than are outside the tracking band.

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12. The method of claim 7, wherein the incision defined by the tracking band results in a capsulotomy.

13. A non-transitory computer-readable medium storing instructions that, when executed, cause a processor of an imaging-based laser system to:

analyze an image of a layer of an eye that is tilted relative to a z-axis of an incision to be made in the eye; determine z-depths of a sequence of points in a scan-pattern that correspond to the layer;

generate a tracking band within the scan pattern defining the incision to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the image of the layer;

generate signals to cause an imaging-based laser-controller system to direct a beam of laser pulses to the points of the scan-pattern to create the incision defined by the tracking band.

14. The computer-readable medium of claim 13, wherein the stored instructions, when executed, cause the processor to: associate a photodisruptive laser-power parameter with points in the scan pattern that are inside the tracking band; and associate a non-photodisruptive laser-power parameter with points in the scan pattern than are outside the tracking band.

15. The computer-readable medium of claim 13, wherein the stored instructions, when executed, cause the processor to perform a feature-recognition analysis to identify the imaged layer.

16. The computer-readable medium of claim 13, wherein the stored instructions, when executed, cause the processor to: generate coordinates of the imaged layer corresponding to the scan pattern and the tracking band; signal the coordinates to a beam scanner; and signal laser-power parameters to a beam attenuator.

17. The computer-readable medium of claim 13, wherein the stored instructions, when executed, cause the processor to signal the laser-power parameters to a beam attenuator by: signaling a photodisruptive laser-power parameter associated with points in the scan pattern that are inside the tracking band; and signaling a non-photodisruptive laser-power parameter associated with points in the scan pattern than are outside the tracking band.

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EXHIBIT 4



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(54) IMAGING-CONTROLLED LASER SURGICAL SYSTEM

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See application file for complete search history.	

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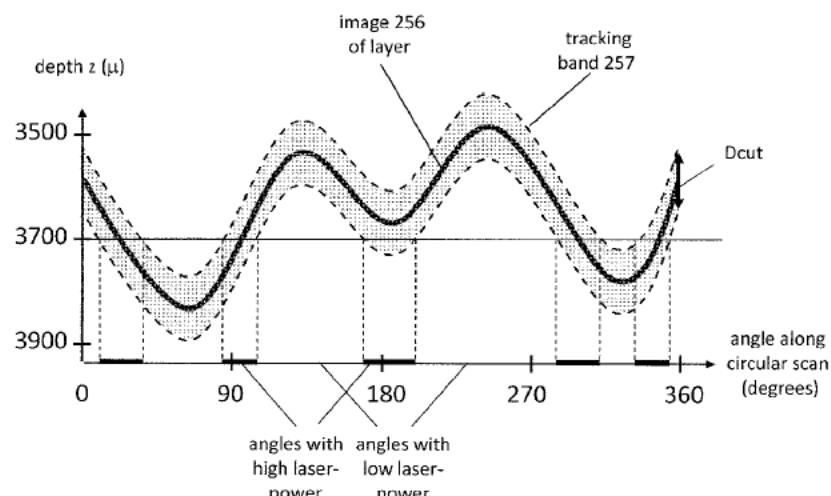
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(57)

ABSTRACT

An imaging-based laser system can include a laser-beam system, configured to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye, and an imaging-based laser-controller, configured to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

29 Claims, 26 Drawing Sheets



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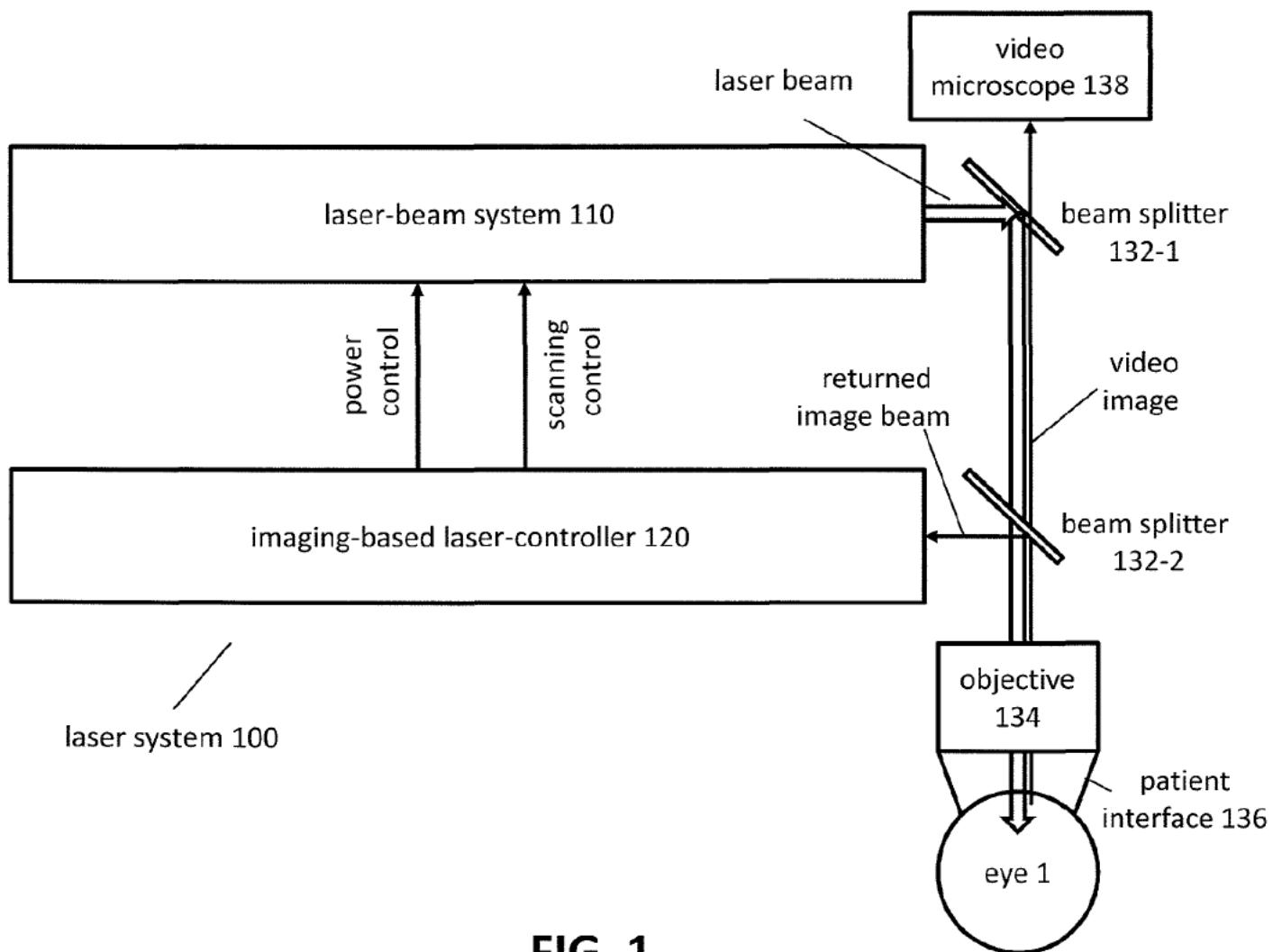


FIG. 1

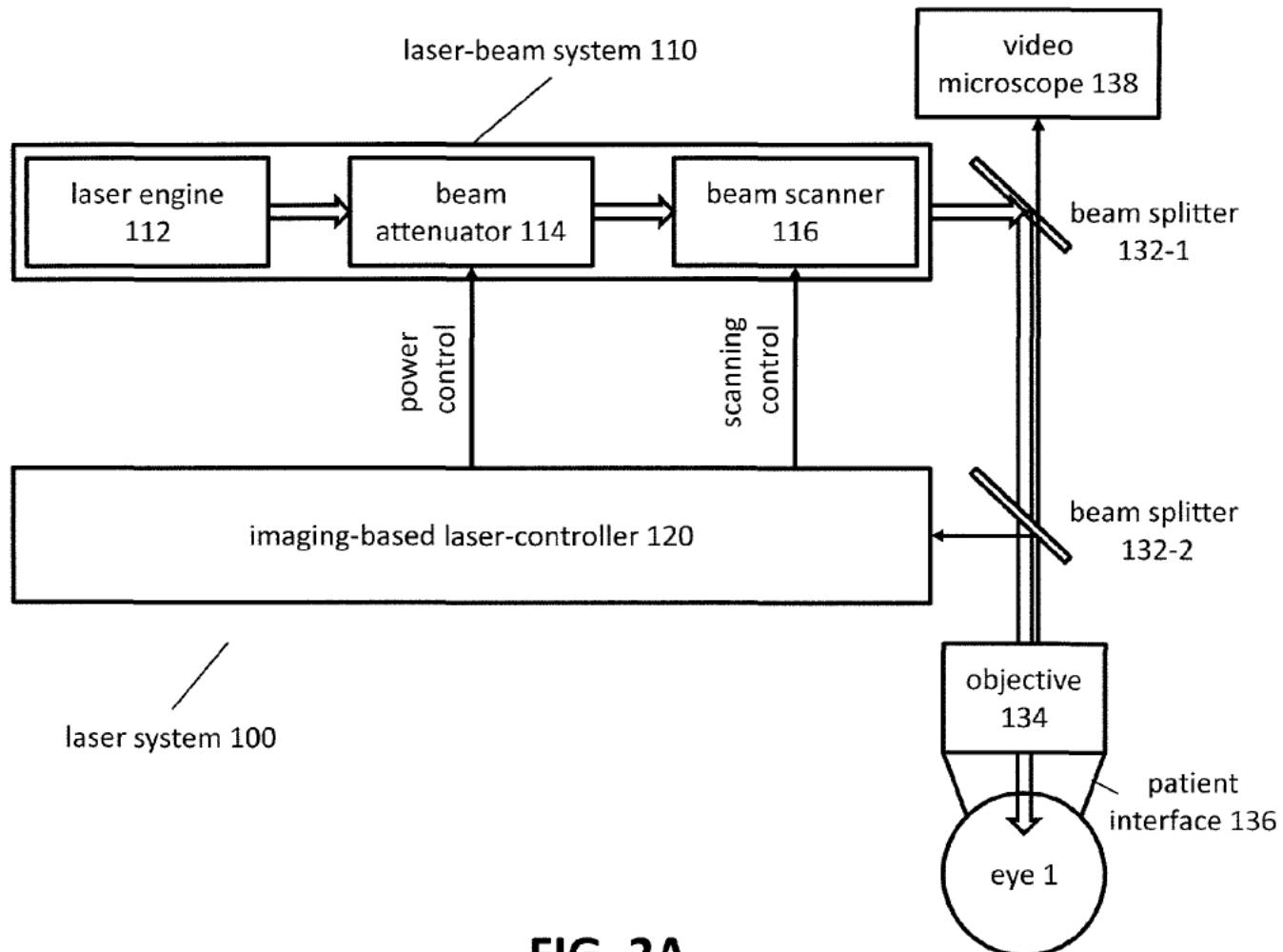
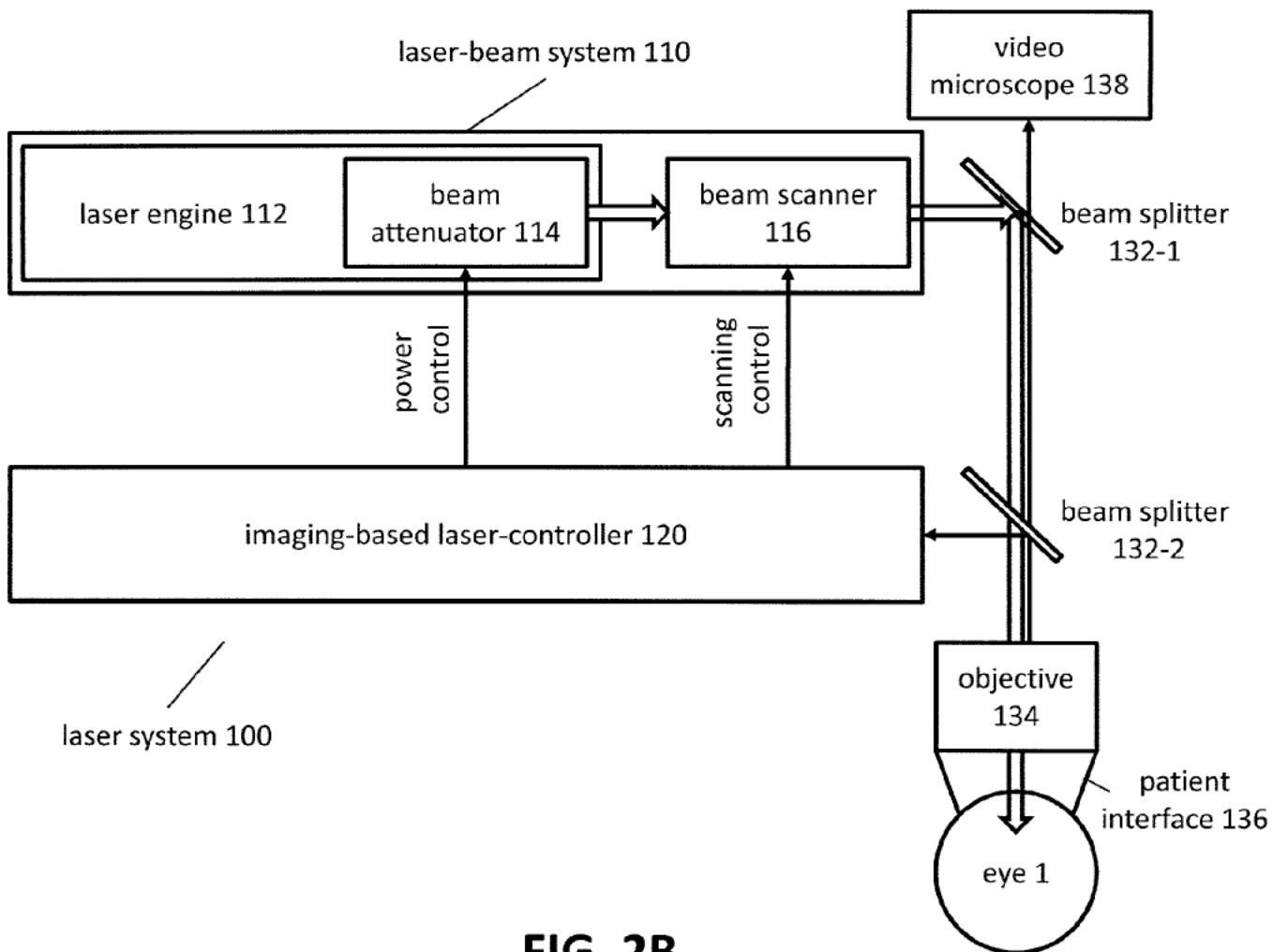


FIG. 2A

**FIG. 2B**

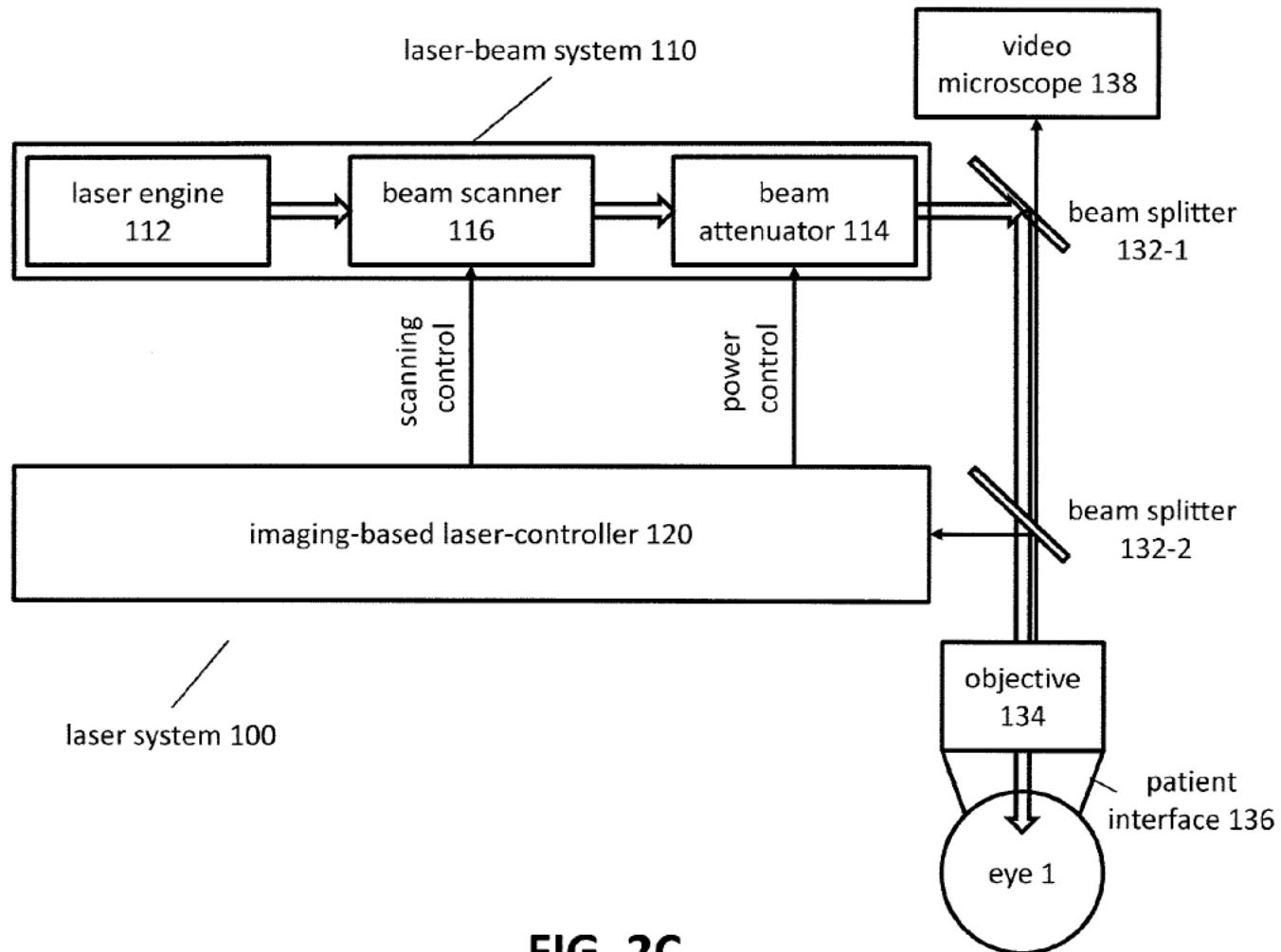


FIG. 2C

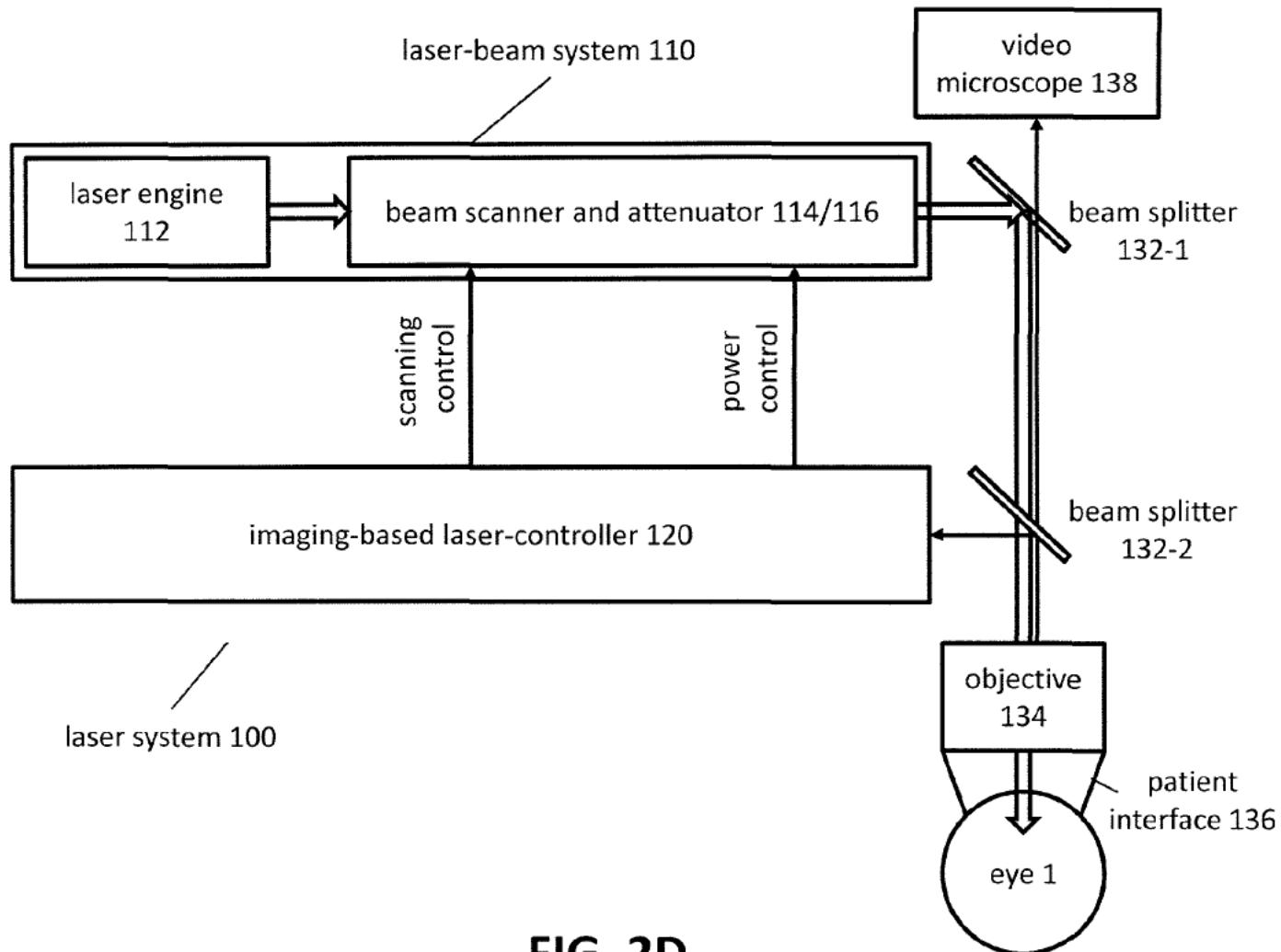


FIG. 2D

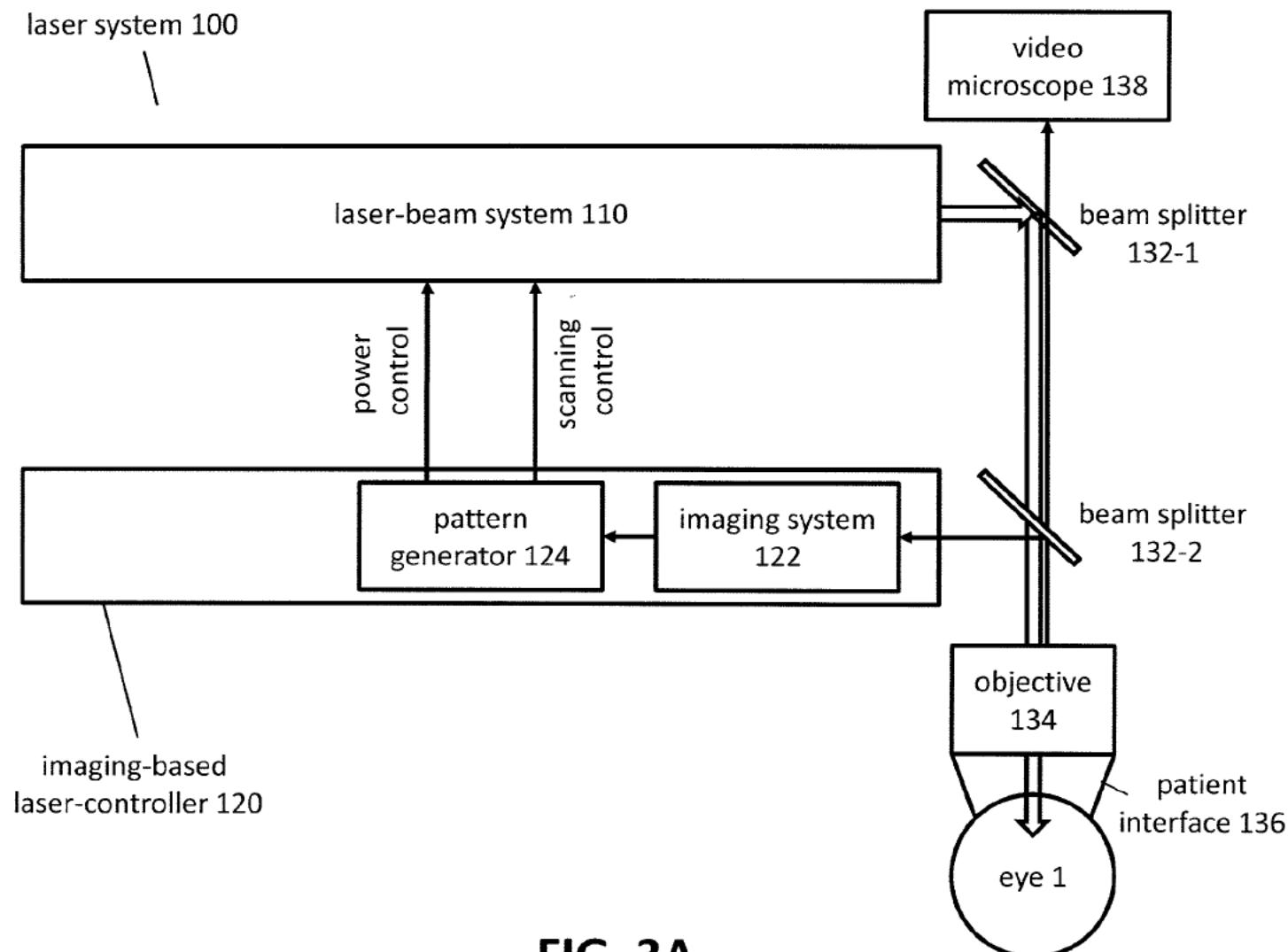


FIG. 3A

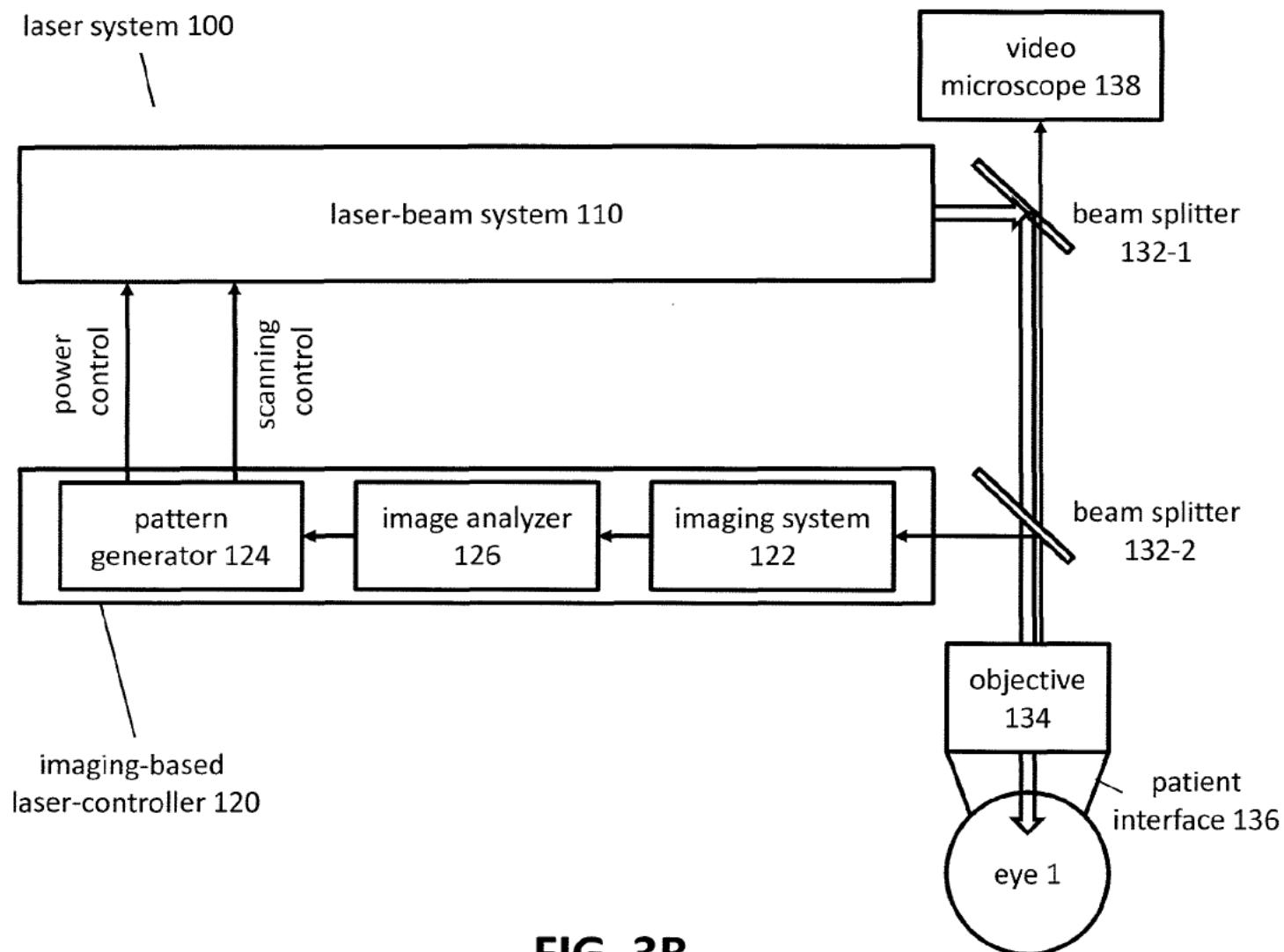


FIG. 3B

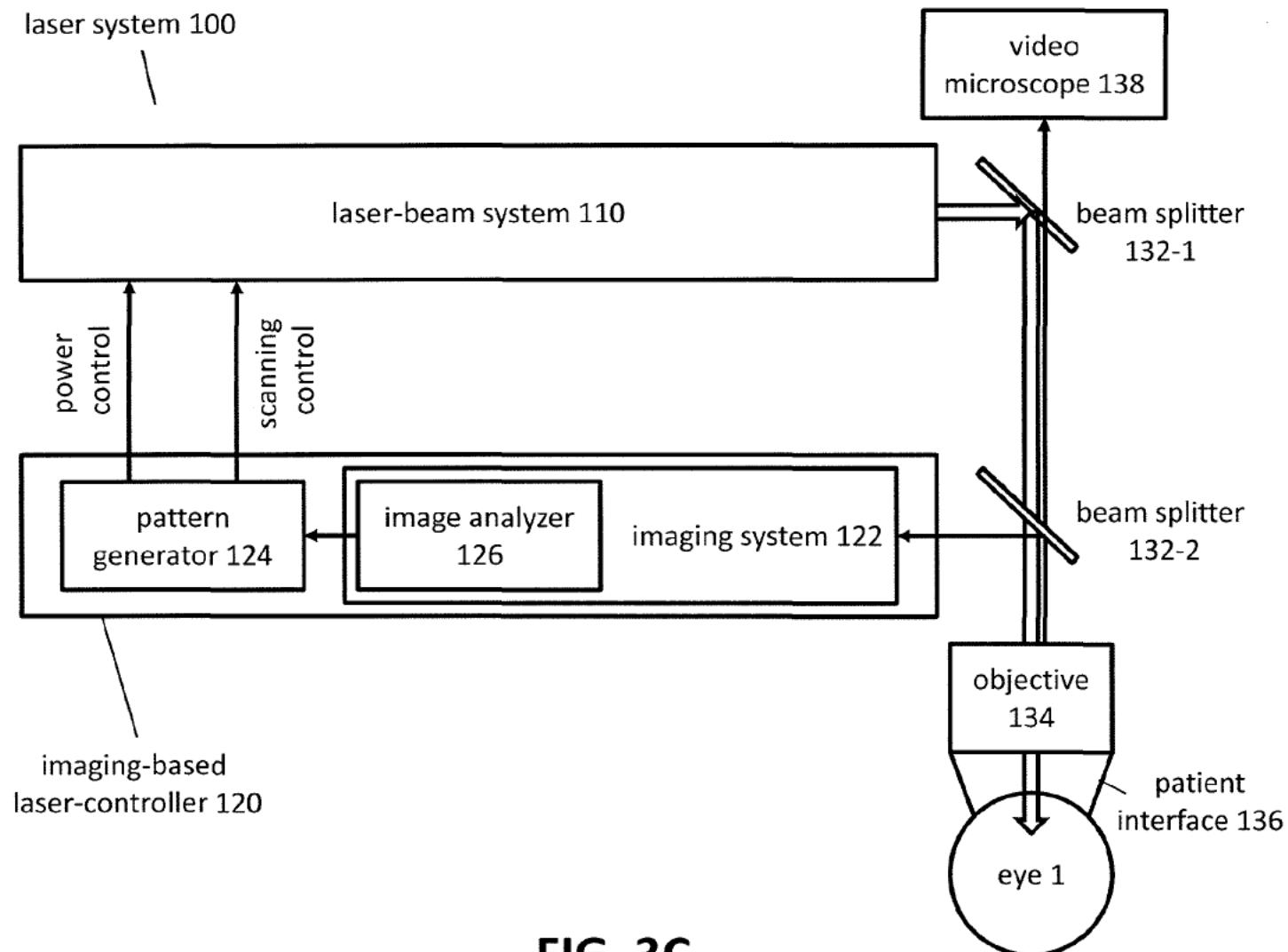


FIG. 3C

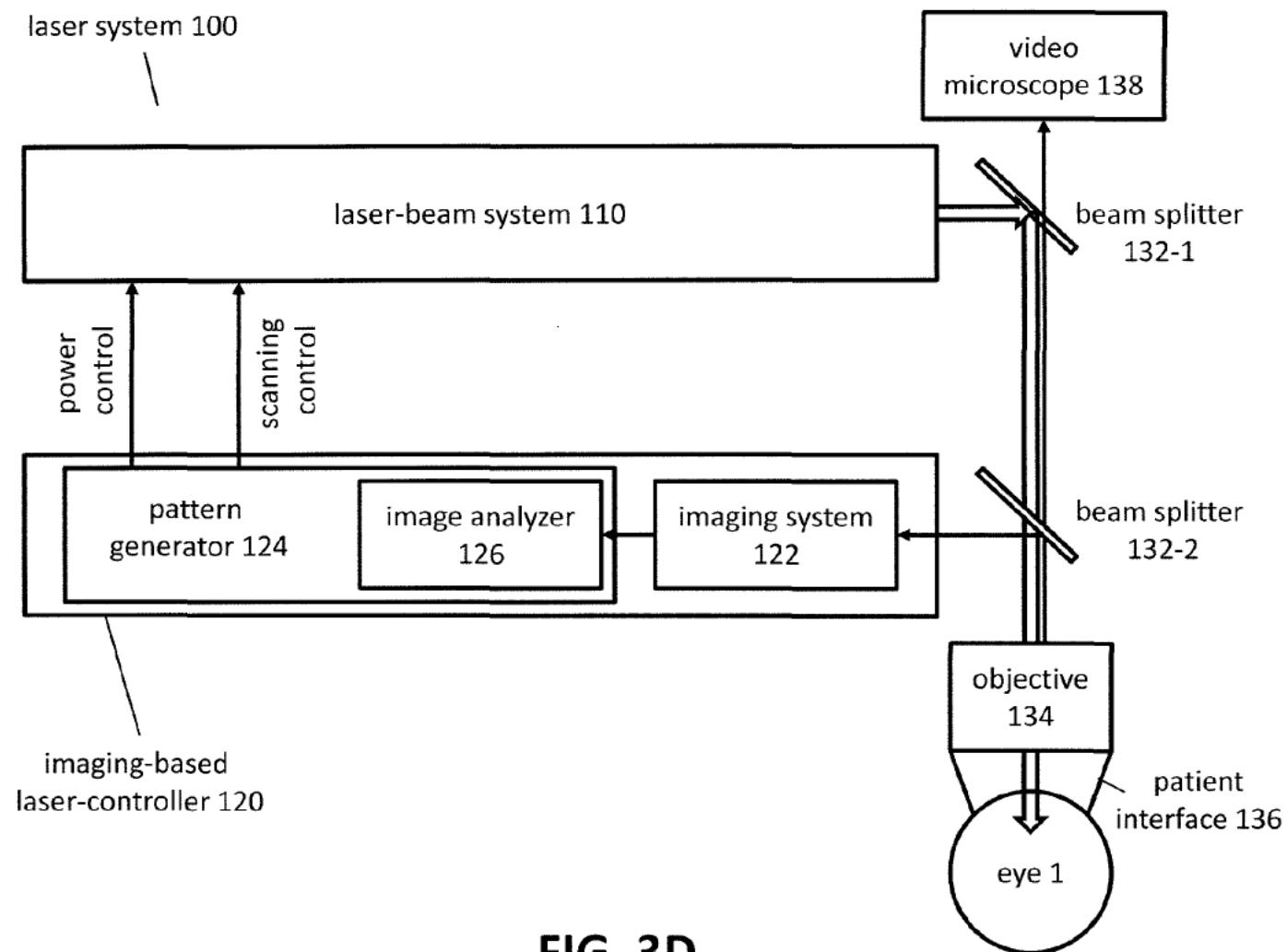


FIG. 3D

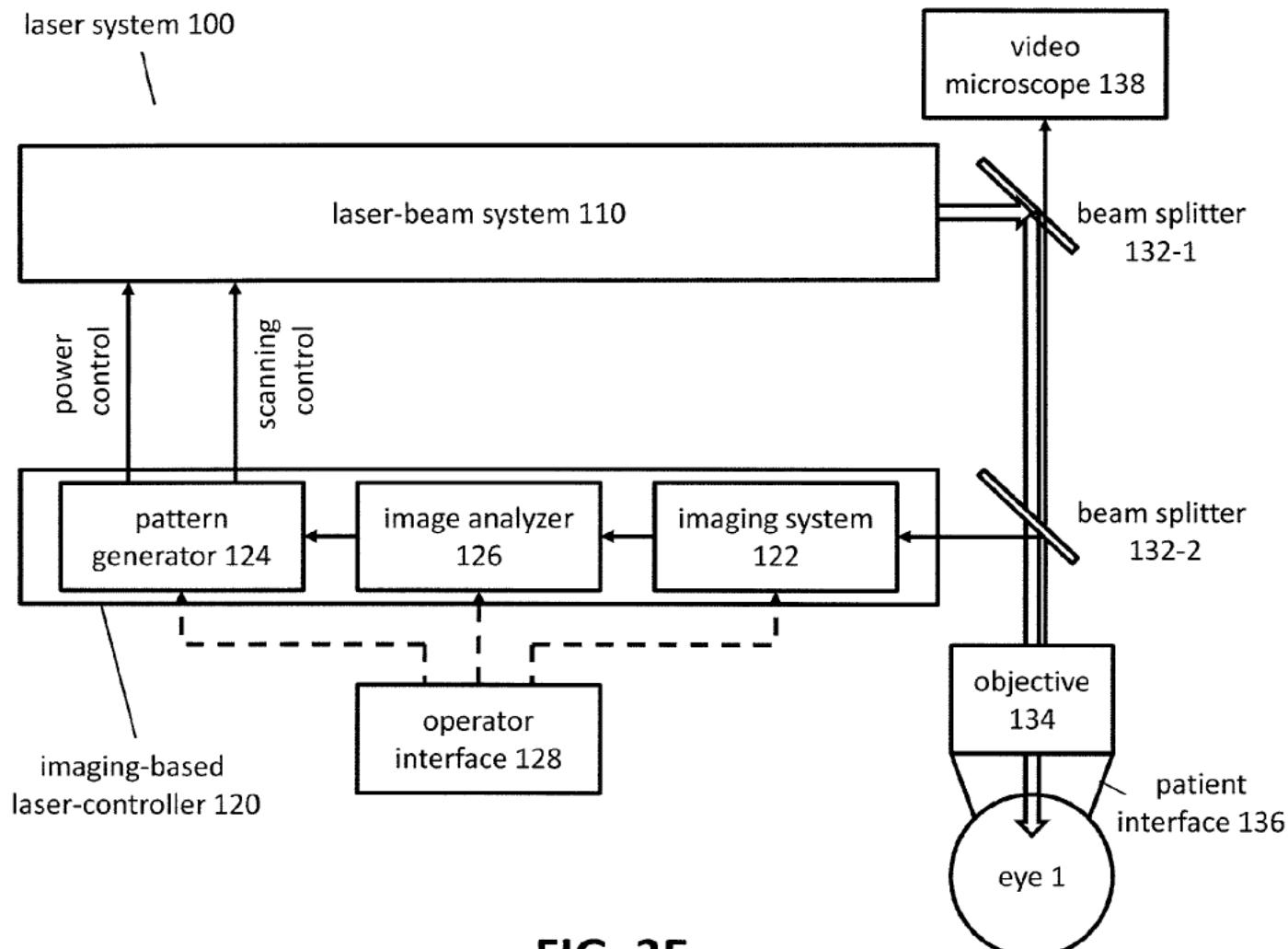


FIG. 3E

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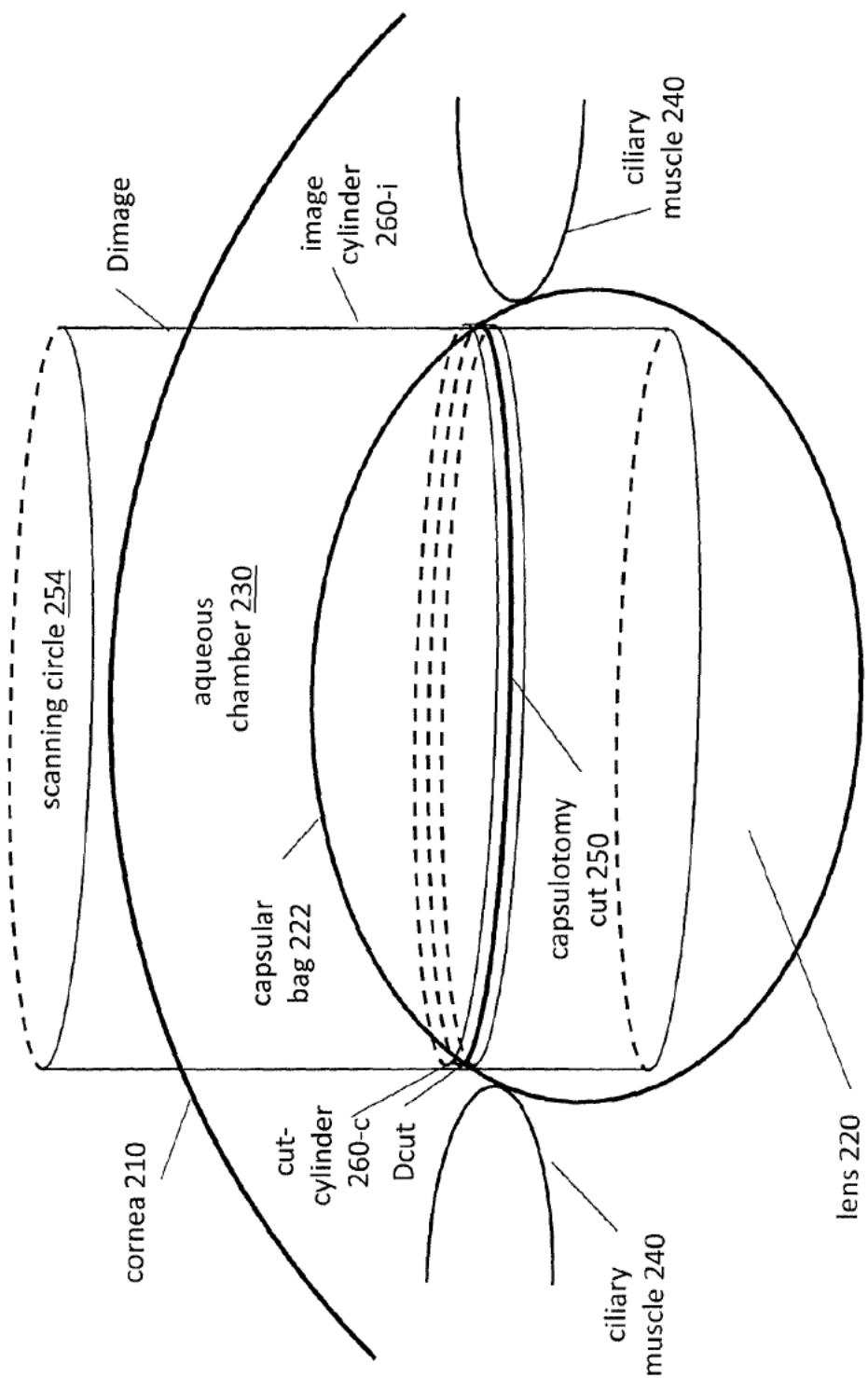


FIG. 4A

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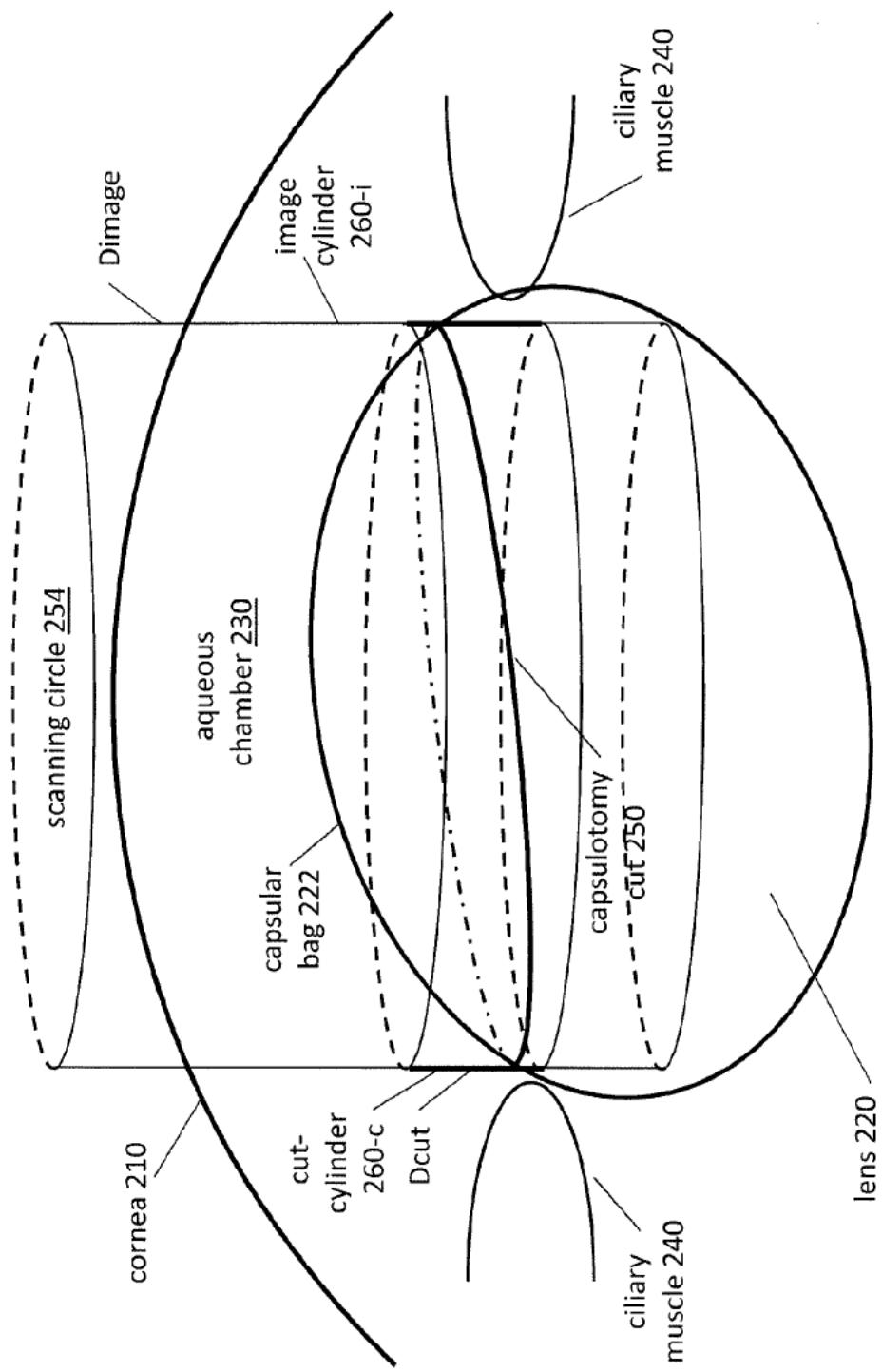
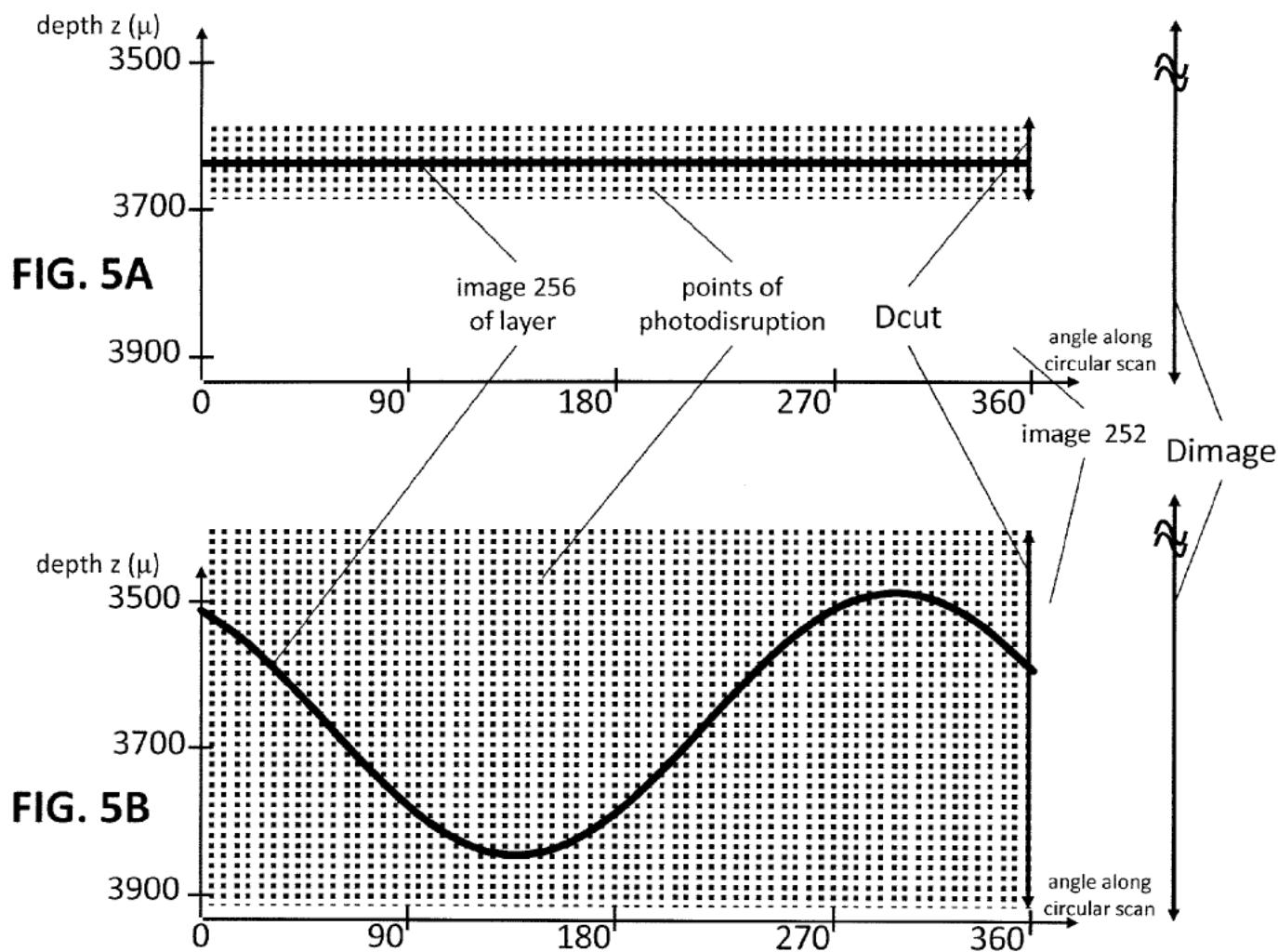


FIG. 4B



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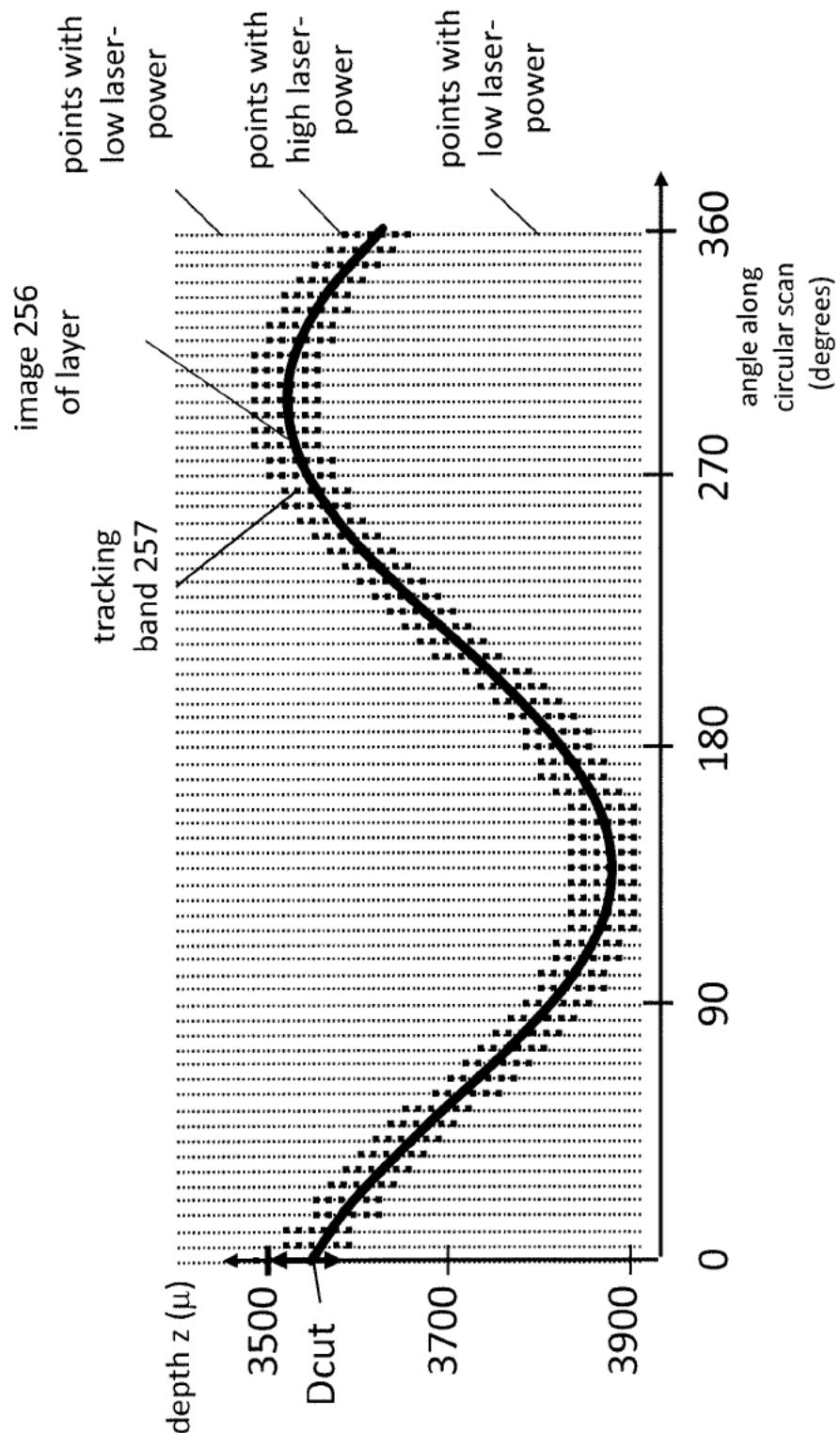


FIG. 6A

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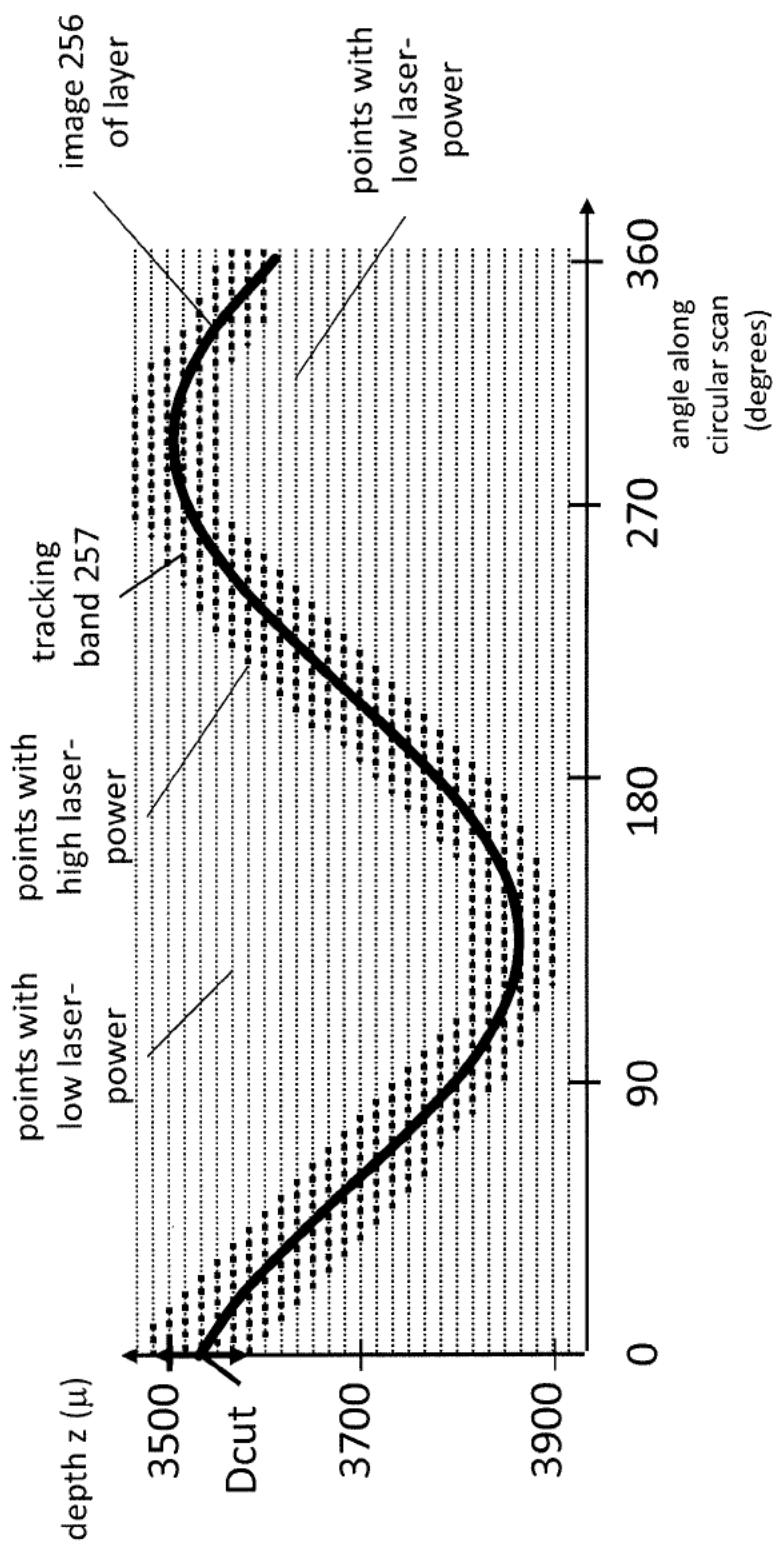


FIG. 6B

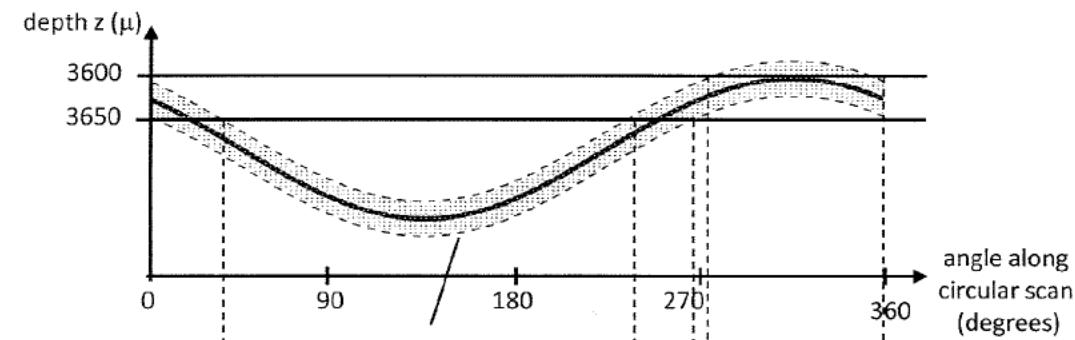


FIG. 6C

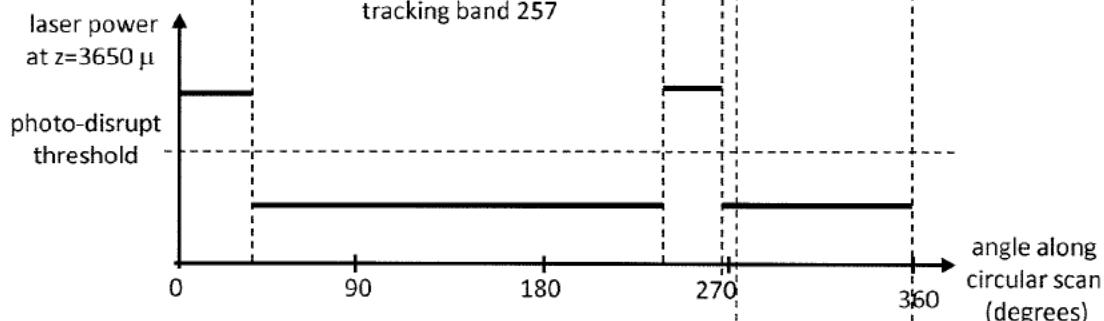


FIG. 6D

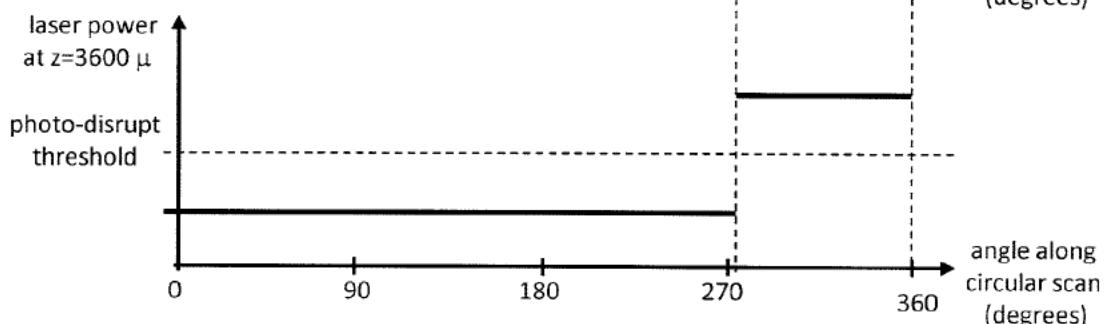


FIG. 6E

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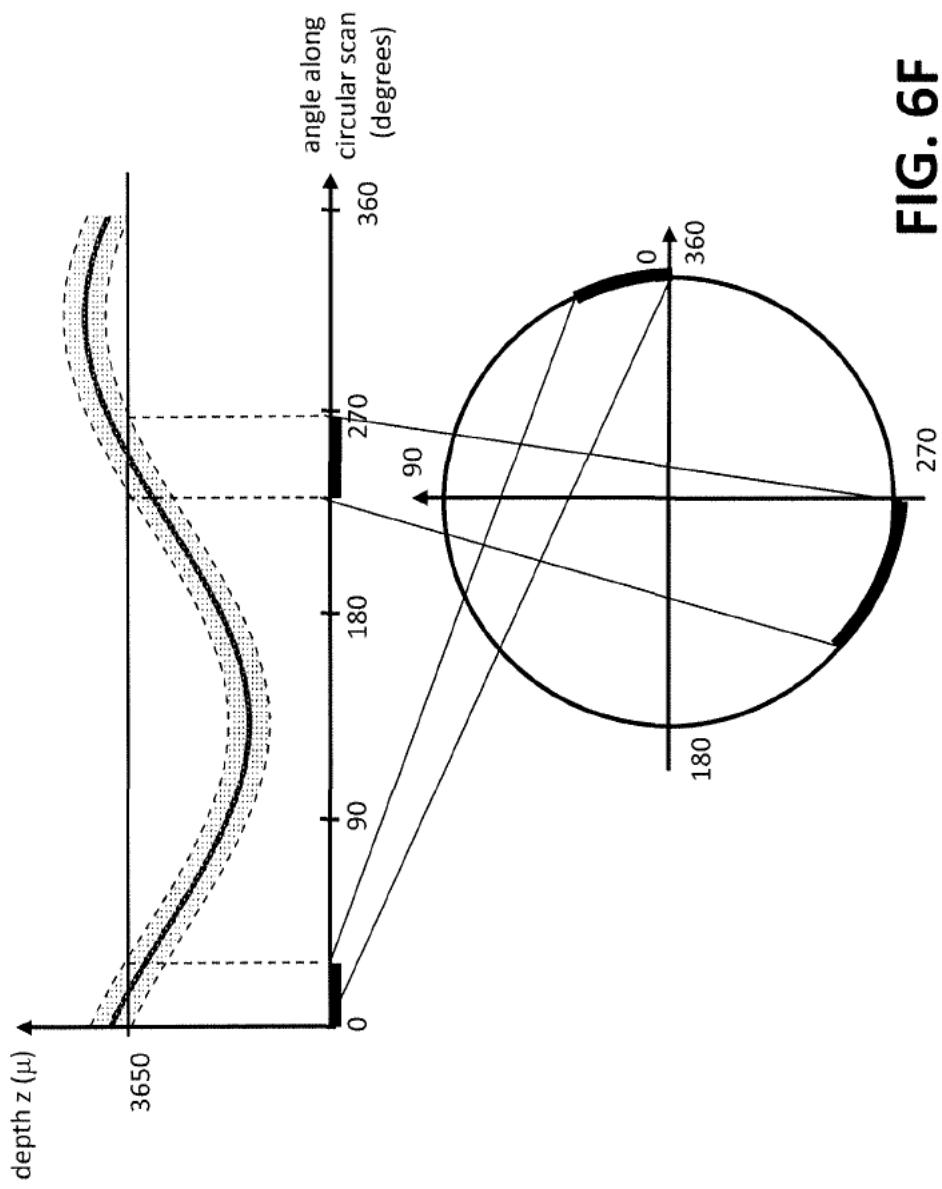


FIG. 6F

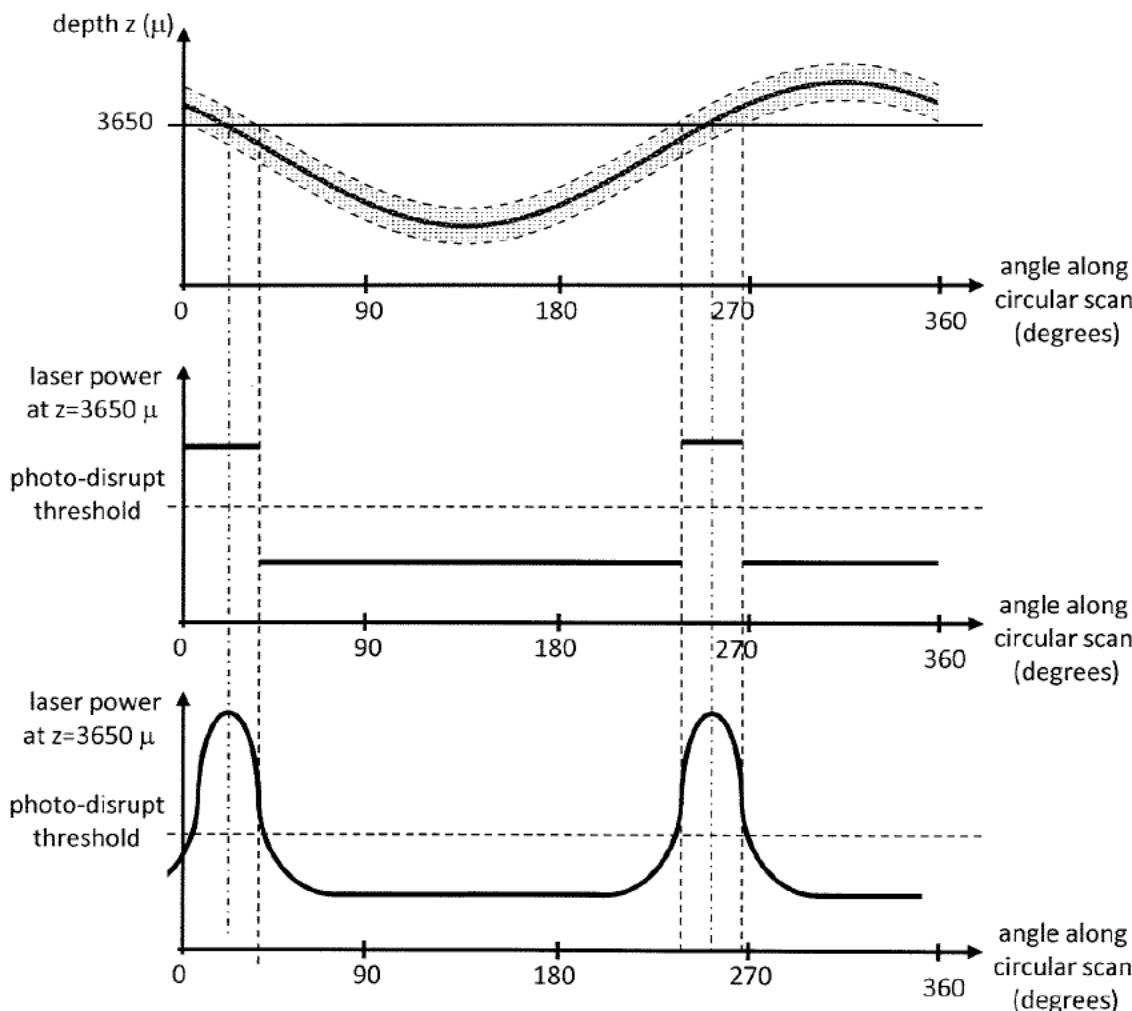


FIG. 6G

FIG. 6H

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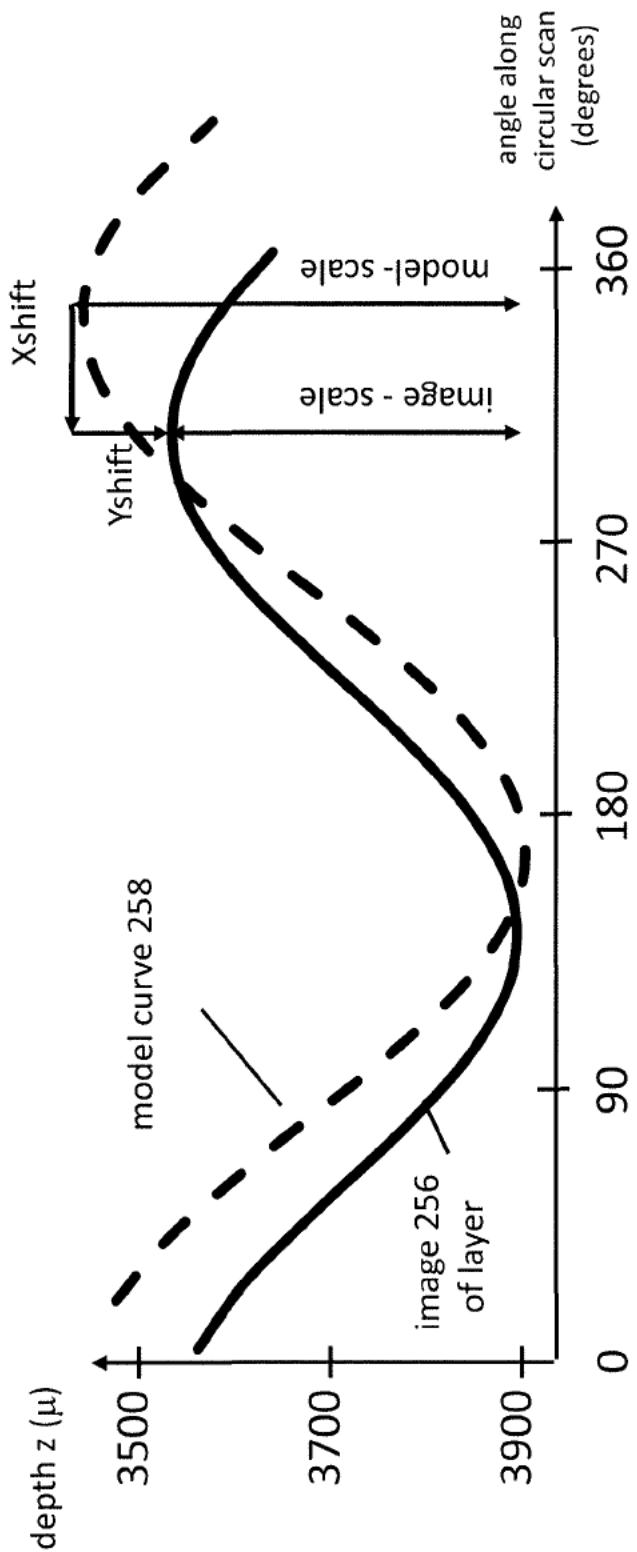


FIG. 7

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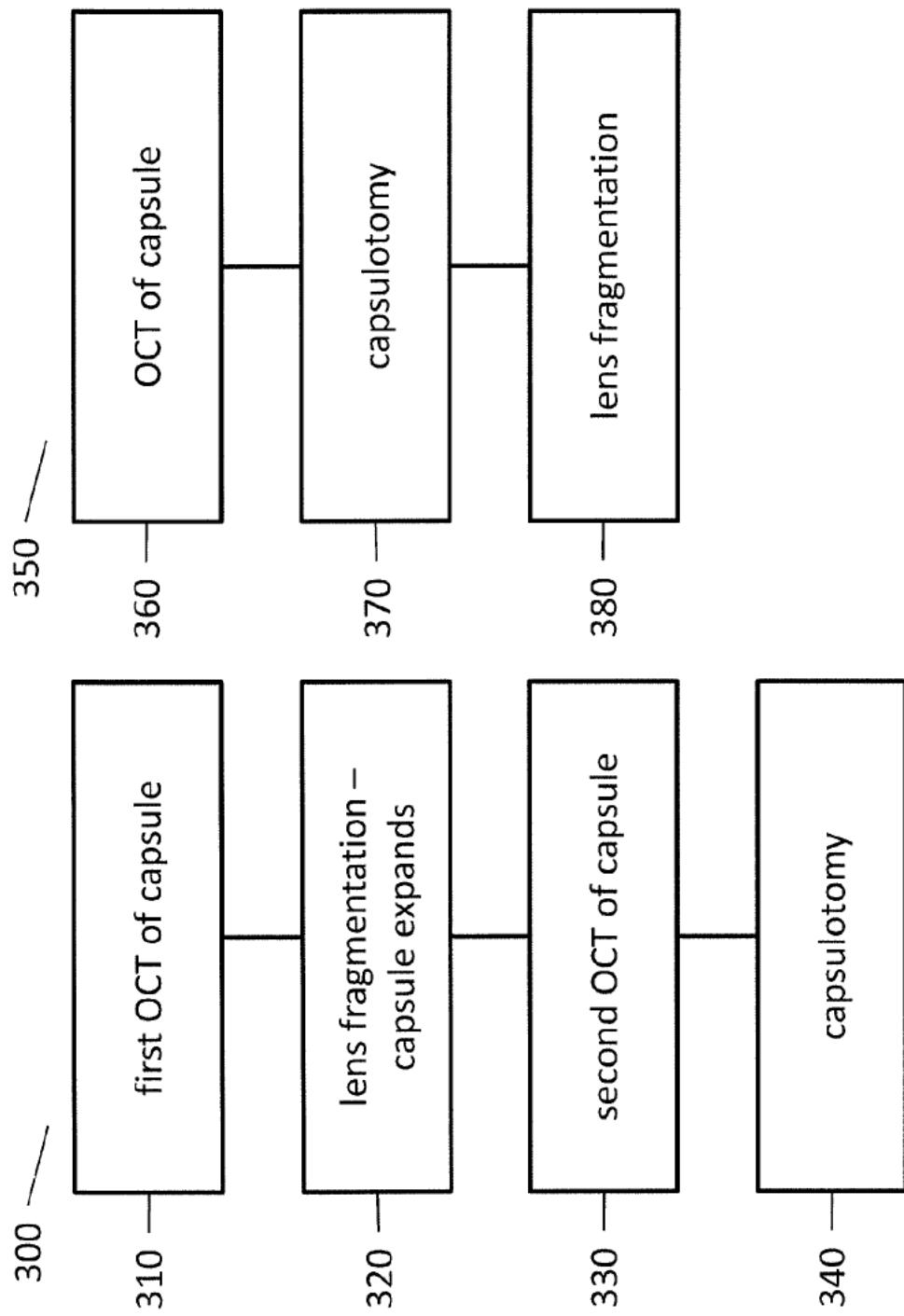


FIG. 8B

FIG. 8A

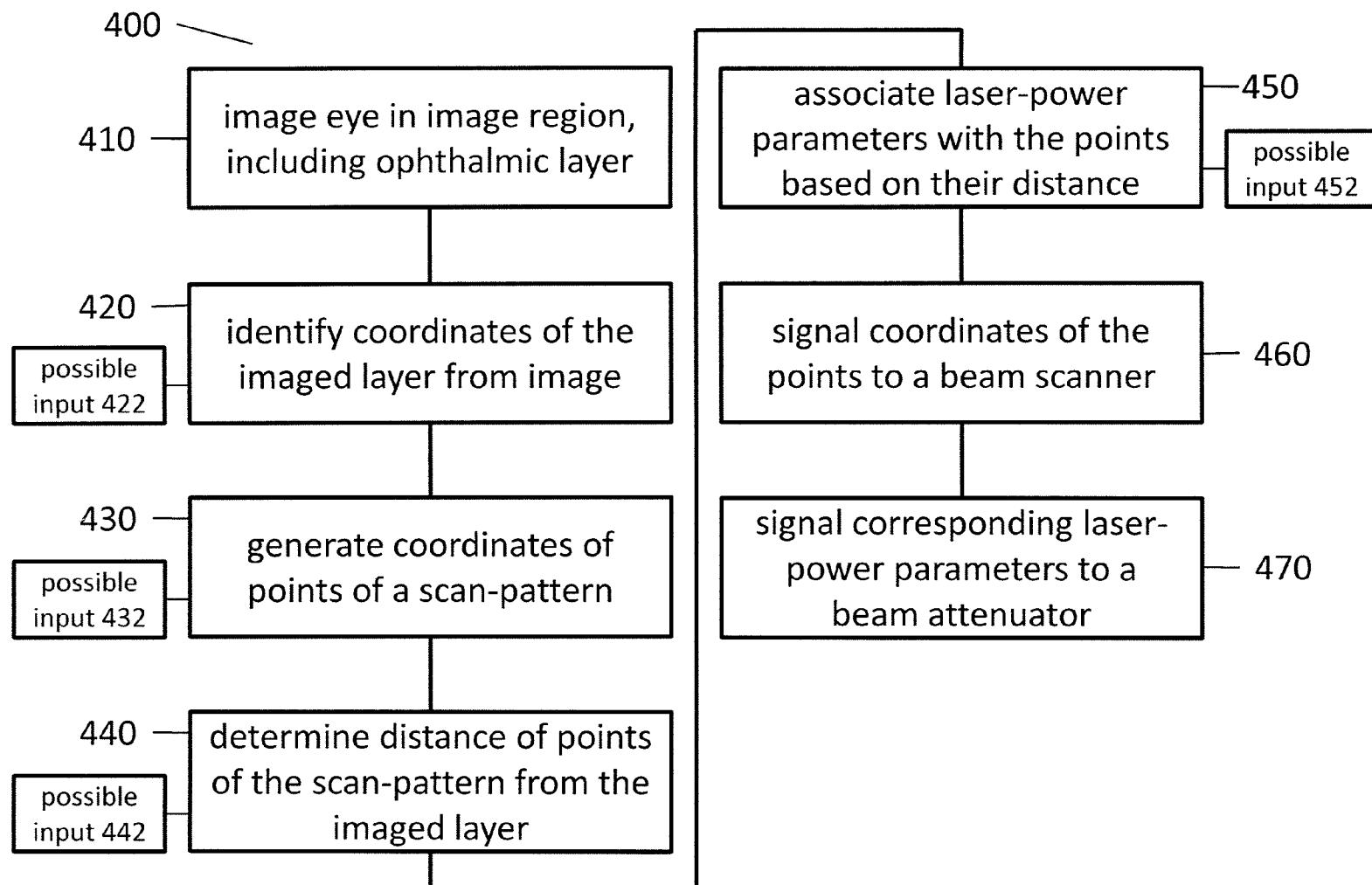


FIG. 9

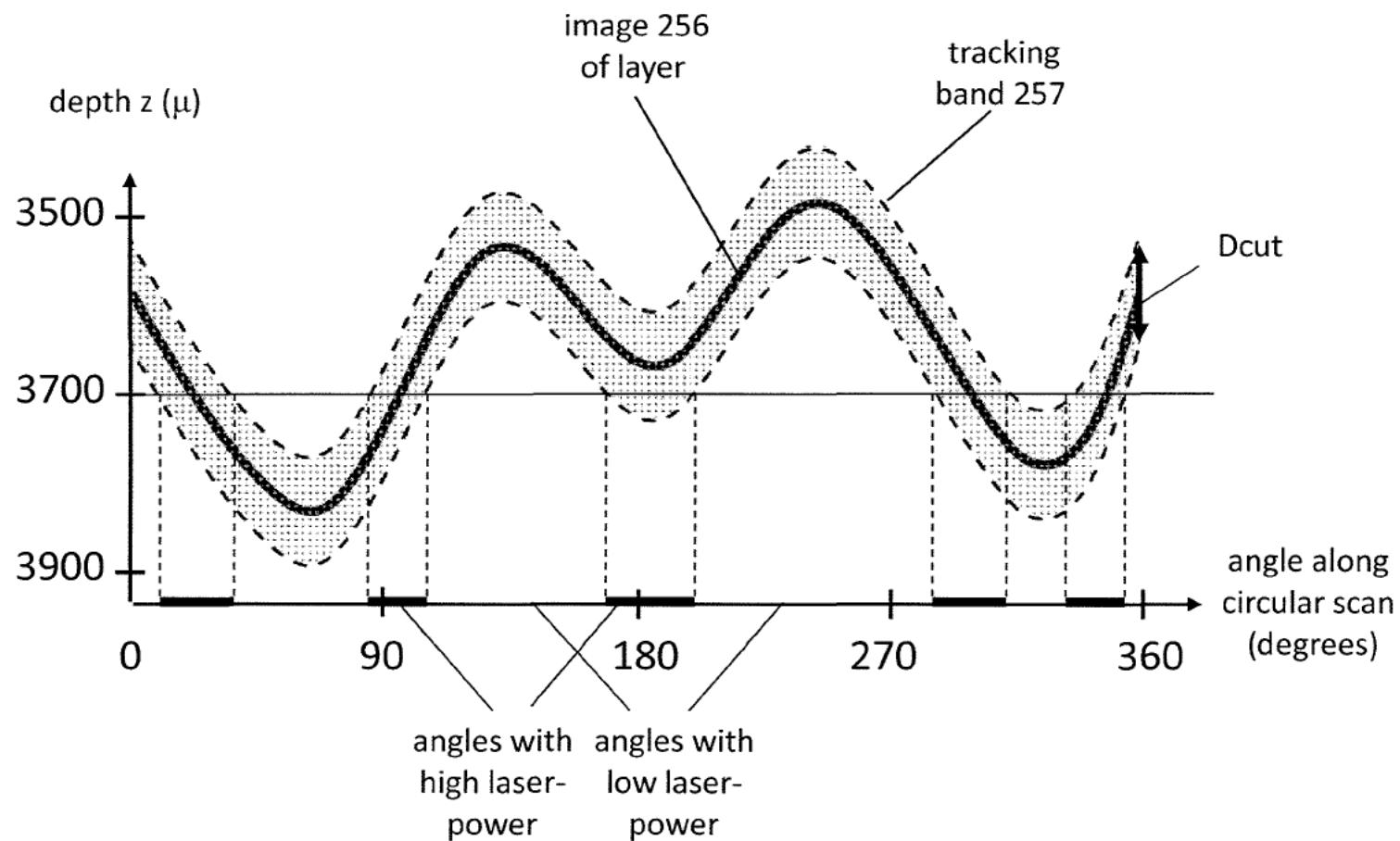


FIG. 10

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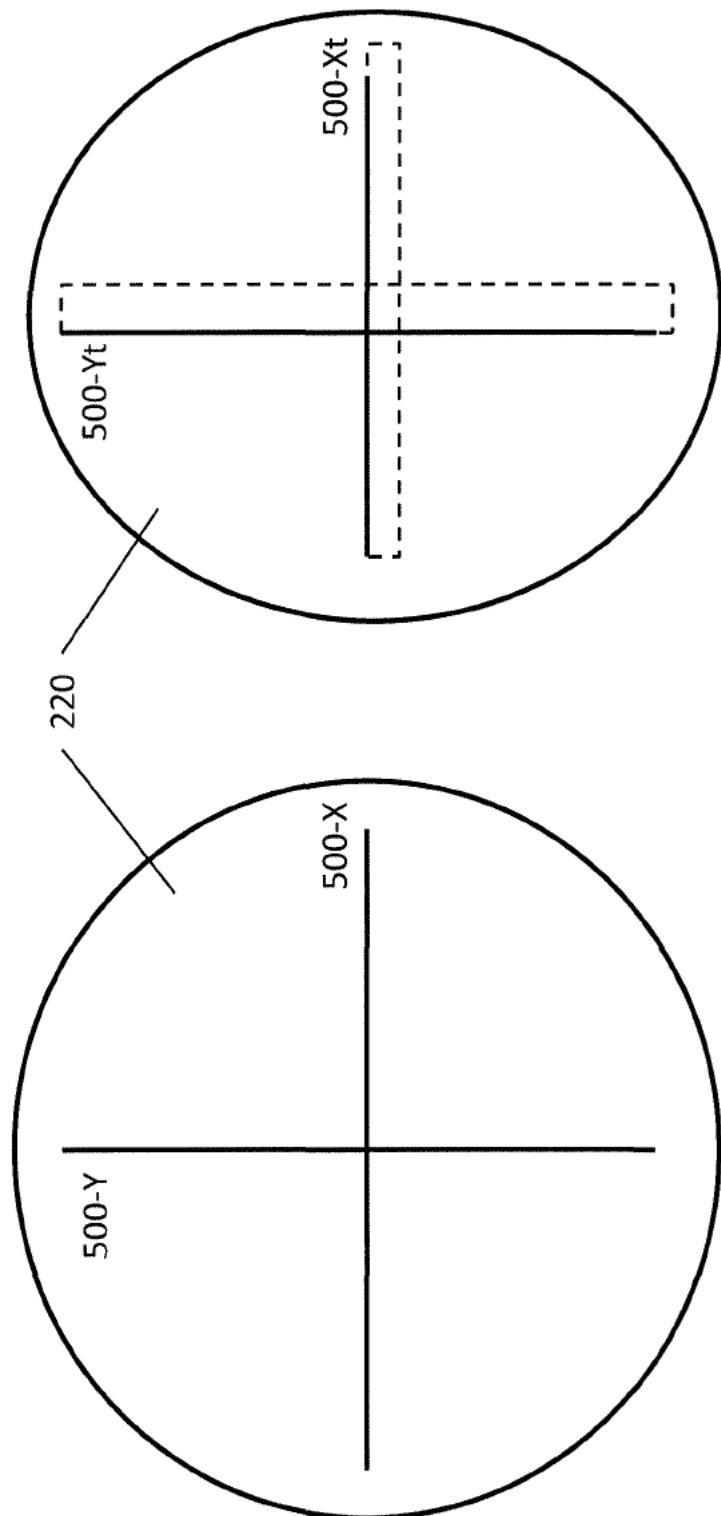


FIG. 11B

FIG. 11A

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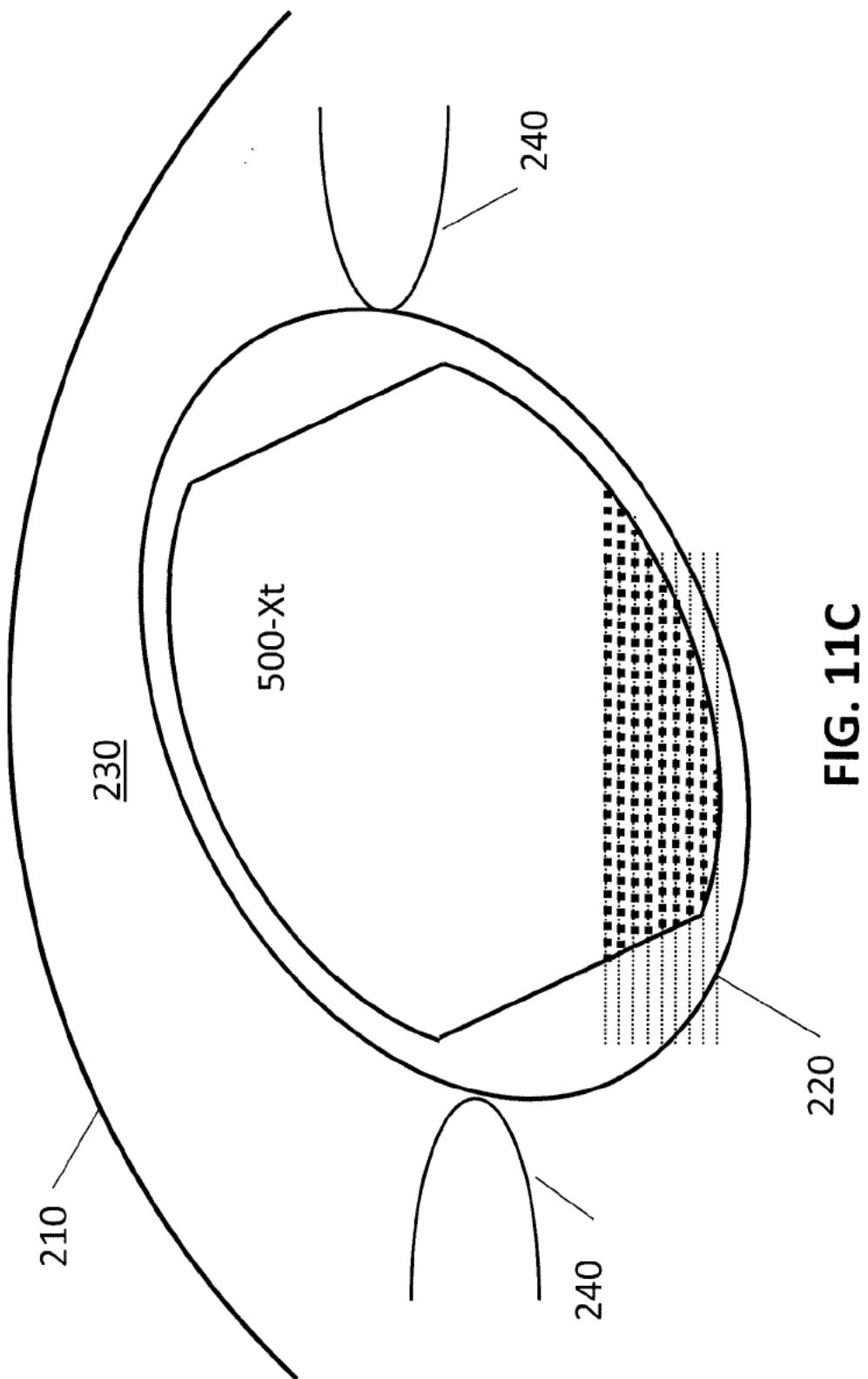


FIG. 11C

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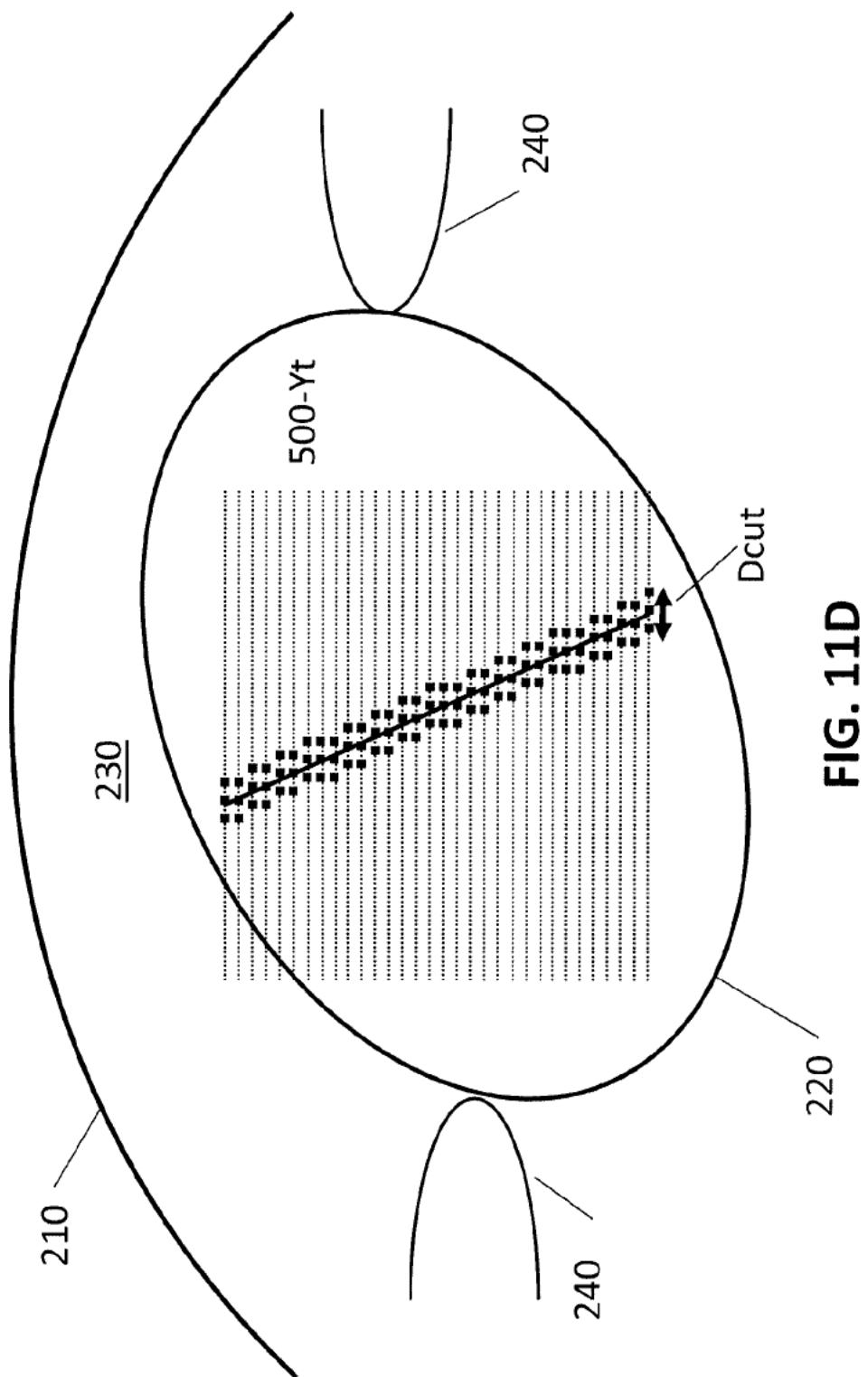


FIG. 11D

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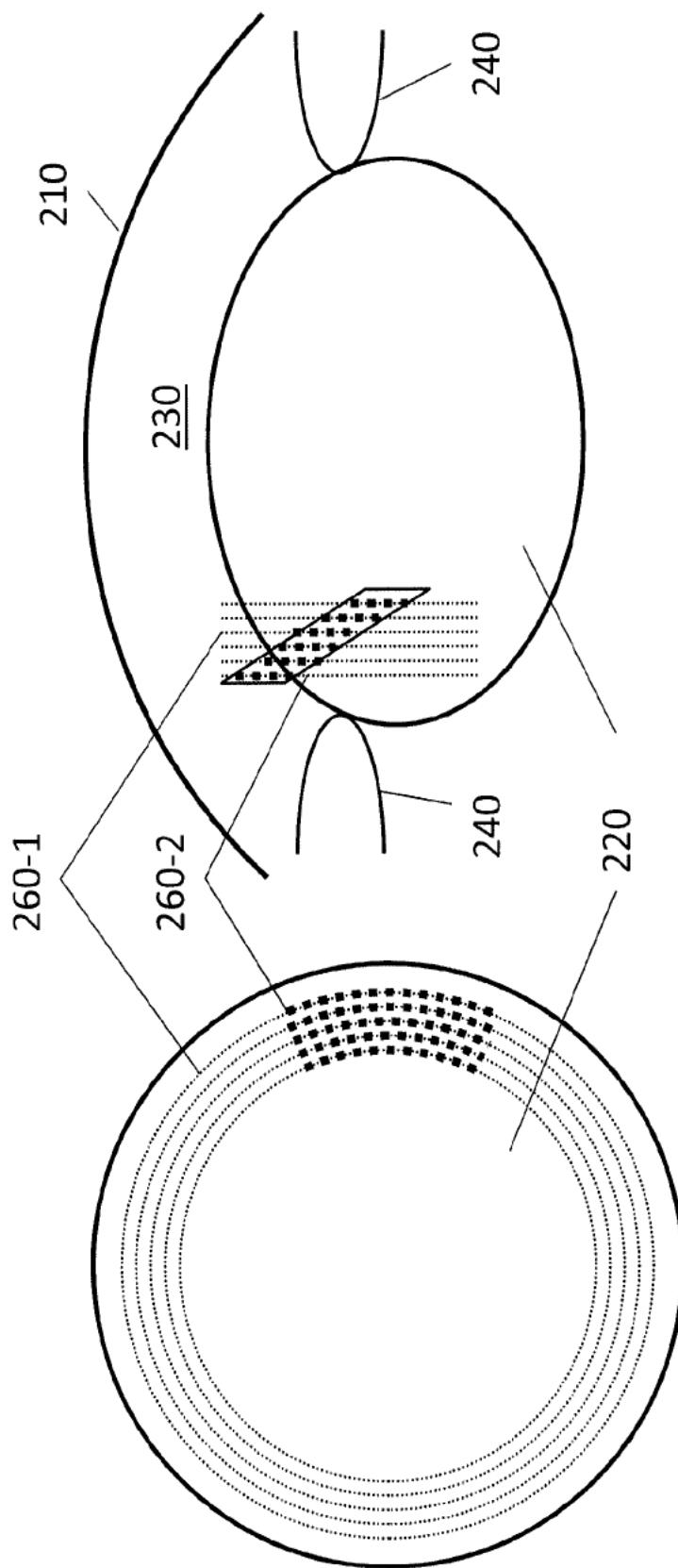


FIG. 12B

FIG. 12A

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IMAGING-CONTROLLED LASER
SURGICAL SYSTEM

TECHNICAL FIELD

This patent document describes a system and method for controlling a laser in an ophthalmic procedure. In more detail, this patent document describes an imaging-controlled laser system for controlling the power of a pulsed ophthalmic laser during capsulotomy and cataract procedures, among others.

BACKGROUND

Laser systems have become essential for ophthalmic surgery. They have been employed in corneal procedures for some time now with high precision and therefore considerable success. In very recent times applications for other ophthalmic procedures have been contemplated, including cataract procedures.

Lasers can be used for forming high precision cuts. These cuts are created by focusing or directing a rapid sequence of laser pulses to a scan-pattern or point-pattern. The points of the scan-pattern often form a line or layer and the laser pulses are directed to these points by a scanning system that includes deflection devices, mirrors and lenses whose alignment can be changed very quickly. In typical laser systems the pulses can have a duration or pulse length in the nanosecond, picosecond, or even femtosecond range. The pulse repetition rate can be in the kHz to hundreds of kHz range.

The power or energy of the laser pulses can be chosen to exceed a so-called photodisruption threshold. Laser pulses with a power above this threshold can disrupt the ophthalmic tissue at the target points, inducing the formation of bubbles. Lines or layers of these bubbles can weaken the mechanical connection between the tissue-portions on the opposite sides of the bubbles. Often the weakening is substantial, effectively cutting the tissue. Therefore, a subsequent manual procedure can completely separate the tissue portions with ease.

One ophthalmic procedure which could benefit from using such a high precision laser cutting system is cataract surgery. A typical cataract surgery involves a capsulotomy step and a lysis or lens fragmentation step. During lysis, energy is applied to a lens nucleus to liquefy it. During lens fragmentation, or phaco-fragmentation, the nucleus of the lens can be cut into several pieces by scanning the laser along cutting surfaces to enable the subsequent piece-by-piece removal of the nucleus. The capsulotomy involves forming a circular cut on the anterior portion of the capsular bag of the lens to allow the surgeon to access and remove the cut-up pieces of the nucleus.

To optimize surgical laser systems for these complex ophthalmic procedures is a great challenge. However, the optimization promises great returns in terms of the precision and efficacy of the surgical procedures.

SUMMARY

One of the challenges of laser cataract surgery is that the procedures of capsulotomy and lens fragmentation can interfere with each other. In advanced laser systems the precision of the surgery can be enhanced by imaging the ophthalmic target tissue prior to the surgery and guide the laser pulses based on the image. If the lens fragmentation is performed first, then, as a surgical by-product, the capsule is expanded

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considerably and unevenly by the substantial amount of bubbles formed inside the capsule. Therefore, after the lens fragmentation, the capsule and lens has to be imaged for a second time to guide the subsequent circular cut of the capsulotomy. However, imaging the severely photodisrupted and distorted lens can be challenging. Also, the repeated imaging procedure consumes precious surgical time, increasing the discomfort of the patient, potentially undermining the precision of the entire procedure.

On the other hand, if the capsulotomy is performed first, it creates a substantial amount of bubbles in the anterior region of the lens and in the anterior aqueous chamber of the eye. The amount of bubbles is especially high if the lens is in a tilted position before the procedure, as explained below. These bubbles can increase the scattering of the laser pulses of the subsequent lens fragmentation considerably as the subsequent pulses are directed to the inside of the lens and thus propagate through the bubble-rich anterior region. The increased scattering can again potentially undermine the precision of the cataract procedure.

Thus, both sequences of the lens fragmentation and capsulotomy have drawbacks, as the first step can reduce the precision and control of the subsequent step. Therefore, laser systems that reduce, resolve, or eliminate one or more of these drawbacks can offer advantages.

Embodiments of the present invention can provide advantageous functionalities in view of these challenges. In particular, an embodiment of an imaging-based laser system can include a laser-beam system, configured to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye, and an imaging-based laser-controller, configured to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

An implementation of an imaging-based laser system can include a laser that generates and directs a beam of laser pulses into an eye, an imaging system that images a capsule layer of the eye, and a laser control system that controls the laser to direct the beam to spots within a tracking band of the imaged capsule layer with a laser-power parameter above a photo-disruption threshold, and to spots outside the tracking band of the imaged capsule layer with a laser-power parameter below a photo-disruption threshold, wherein the image-based laser system is configured to perform a capsulotomy before a lysis or lens- or phaco-fragmentation during a cataract procedure.

An implementation of an image-guided ophthalmic laser system can include a laser engine, configured to generate laser pulses, a beam modifier, configured to modify a laser-power parameter of the laser pulses, a laser scanner, configured to direct the laser pulses to scanning-points in an eye, an imaging system, configured to image a region in the eye, and a pattern generator, coupled to the imaging system, the beam modifier and the laser scanner, configured to generate coordinates of the scanning-points for the laser scanner, and to associate a laser-power parameter with the scanning-points depending on a distance of the scanning-points from a target-pattern.

In some implementations, a method of performing an imaging-controlled ophthalmic procedure can include imaging a layer in an eye, generating coordinates of points of a scan-pattern, determining a distance of the points of the scan-pattern from the imaged layer, and associating laser-power parameters with the points based on the determined distance.

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BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an embodiment of a surgical laser system with an imaging-controlled laser system

FIGS. 2A-D illustrate embodiments of the laser-beam system.

FIGS. 3A-E illustrate embodiments of the imaging-based laser controller.

FIGS. 4A-B illustrate the scan-patterns for non-tilted and tilted lenses.

FIGS. 5A-B illustrate traditional scan-patterns for non-tilted and tilted lenses as a function of a scanning variable.

FIGS. 6A-H illustrate a scan-pattern along a circular scan with a distance-dependent laser-power parameter.

FIG. 7 illustrates a determination of the z-depth of the imaged layer by using a model curve.

FIG. 8A-B illustrate methods of cataract surgery with the lens fragmentation and capsulotomy in different sequences.

FIG. 9 illustrates a method of cataract surgery with an imaging-controlled laser system in detail.

FIG. 10 illustrates a multi-extrema tracking-band laser scan-pattern after lens-fragmentation expanded the lens capsule in a non-uniform manner.

FIGS. 11A-D illustrate scan-patterns for tilted chop cuts.

FIGS. 12A-B illustrate scan-patterns for tilted volume cuts.

DETAILED DESCRIPTION

Implementations and embodiments described in this patent document offer improvements for the above described challenges.

FIG. 1 illustrates an imaging-based laser system 100, including a laser-beam system 110 to generate and scan a beam of laser pulses with an adjustable laser-power parameter to points of a scan-pattern in an eye 1, and an imaging-based laser-controller 120 to image a layer in the eye, to control the scanning of the beam of laser pulses to the points of the scan-pattern, and to control a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer. The laser-controller 120 can perform these functions by sending a power control signal and a scanning control signal to the laser-beam system 110, for example.

The laser beam of the laser-beam system 110 can be guided into the main optical pathway at a beam-splitter 132-1 that can redirect the beam to an objective 134. The beam can propagate through the objective 134 and through a patient interface 136 to enter into the surgical eye 1.

The surgery can be assisted by imaging the eye 1 with various techniques. A visible imaging light can be used to create a video image that is processed by a video microscope 138. In addition, the imaging-based laser-controller 120 can shine an imaging beam on the eye and form an image based on the returned image beam. This imaging beam can be coupled into and out of the main optical path by a beam-splitter 132-2.

FIGS. 2A-D illustrate various embodiments of the laser-beam system 110.

FIG. 2A illustrates that embodiments of the laser-beam system 110 can include a laser engine 112 to generate the beam of laser pulses, a beam attenuator 114 to modify the laser-power parameter of the laser pulses, and a beam scanner 116 to direct the beam of laser pulses to the points of the scan-pattern in the eye. The laser engine 112 can generate laser pulses with a duration of nanoseconds, picoseconds or even femtoseconds, i.e. in the 10^{-9} - 10^{-15} sec

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range. These pulses can be generated at a repetition rate in a wide range of frequencies: from 0.1 kHz to 1,000 kHz, or in a range of 1 kHz to 500 kHz, or in some implementations in the 10 kHz to 100 kHz range. The power control signal of the laser-controller 120 can be coupled into the beam attenuator 114 and the scanning control signal of the laser-controller 120 can be coupled into the beam scanner 116.

The beam attenuator 114 can include a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, or an energy wheel. Each of these implementations can modify a laser-power parameter of the laser pulses. The laser-power parameter can be a pulse energy, a pulse power, a pulse length or a pulse repetition rate of the laser pulses, among others. The beam attenuator 114 can modify one or more of these laser-power parameters. In a simple implementation, the beam attenuator 114 can shutter or block selected laser pulses. In another, a polarizer assembly can reduce the power of selected laser pulses by adjusting the relative angle of subsequent polarizing filters.

In the embodiment of FIG. 2A, the beam attenuator 114 can be located between the laser engine 112 and the beam scanner 116 in the path of the laser beam.

FIG. 2B illustrates and embodiment in which the beam attenuator 114 is at least partially integrated into the laser engine 112. In some cases, the beam attenuator 114 can be part of the laser engine 112. For example, a Pockels cell within the laser engine 112 can be the beam attenuator 114.

FIG. 2C illustrates and embodiment in which the beam attenuator 114 is located after the beam scanner 116 in the path of the laser beam.

Finally, FIG. 2D illustrates an embodiment in which the beam attenuator 114 and the beam scanner 116 are at least partially integrated.

FIGS. 3A-E illustrate various embodiments of the imaging-based laser-controller 120.

FIG. 3A illustrates that the laser-controller 120 can include an imaging system 122 to image the imaged layer in the eye and a pattern generator 124 to generate coordinates of the points of the scan-pattern, to associate laser-power parameters with the points depending on the distance of the points from the imaged layer, and to signal the generated coordinates of the points and the corresponding laser-power parameters to the laser-beam system 110. In some implementations, the imaging system 122 can image any ophthalmic target in the anterior or posterior segment of the eye, targets from the cornea to the retina.

The pattern generator 124 can signal the generated coordinates of the points of the scan-pattern to the beam scanner 116 with a scanning control signal. Further, the pattern generator 124 can signal the laser-power parameters corresponding to the points of the scan-pattern to the beam attenuator 114 with a power control signal. The laser-power parameter can be a pulse energy, a pulse power, a pulse length or a pulse repetition rate of the laser pulses.

The imaging system 122 can include an ophthalmic coherence tomography (OCT) system, a Scheimpflug imaging system, a scanning imaging system, a single shot imaging system, an ultrasound imaging system, and a video imaging system. Here, the scanning imaging systems can create the image by scanning an imaging beam, whereas single shot imaging systems can acquire imaging information about an imaged area or volume in a single shot. The OCT system can be a time-domain OCT, a frequency-domain OCT, or a spectrometer-based OCT system, among others.

FIG. 3B illustrates that in some implementations the laser-controller 120 can include an image-analyzer 126. The

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image analyzer 126 can receive the image of the imaged layer from the imaging system 122, perform an analysis of the imaged layer as described below and forward the result of the analysis to the pattern generator 124.

FIG. 3C illustrates that in some implementations the image analyzer 126 can be at least partially integrated with the imaging system 122. FIG. 3D illustrates that in some implementations the image analyzer 126 can be at least partially integrated with the pattern generator 124.

FIG. 3E illustrates that in some embodiments, the laser system 100 can include an operator-interface 128 that can be coupled to one or more of the imaging system 122, the pattern generator 124 and the image analyzer 126.

FIGS. 4A-B set the stage to illustrate the operation of the laser system 100. The imaging system 122 can image the imaged layer in an image region that can be based on a loop, an arc, a line, or a two-dimensional pattern transverse to a z-axis of the imaging system, and extends to a depth range Dimage along the z-axis of the imaging system. The imaging system 122 can support a determination of a z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image-scan.

FIG. 4A illustrates that the imaging system 122 can perform an imaging relevant for a capsulotomy step of a cataract procedure. The schematic cross section illustrates the anterior segment of the eye 1. The outermost layer is a cornea 210. A crystalline lens 220 is located behind the cornea 210, separated from it by an aqueous anterior chamber 230. The crystalline lens 220 is encapsulated in a thin capsule or capsular bag 222. The lens 220 is held in place by ciliary muscles 240. These muscles 240 also adjust the shape of the crystalline lens 220 as needed for bringing objects into focus.

As it has been described above, in order to facilitate the removal of a fragmented nucleus of the lens 220, the cataract surgery typically involves creating a circular capsulotomy cut 250 on the capsular bag 222. As a first step, the imaging system 122 can create an image 252 of the anterior segment of the eye by scanning along a scanning circle 254 and imaging the eye in a depth-range Dimage, defining an image-cylinder 260-i.

FIG. 5A illustrates that the image 252 typically includes an image 256 of the imaged anterior capsule layer of the lens 220 “unfolded” along a scanning variable, such as an angle along the circumference of the scanning circle 254. If a z-axis of the lens 220 is aligned with a z-axis of the laser system 100, the image 256 of the imaged layer is a flat line, indicating an essentially constant z-depth.

In other implementations, the image 252 can include the image of other ophthalmic targets, including corneal layers, portions of the sclera and even retinal layers. The zero depth level can be defined in a large number of ways, using a lens of the objective 134, a reference mirror of the imaging system 122, a level of the patient interface 136, or a level of an ophthalmic structure, such as the cornea 210.

By analyzing the image 252, a surgeon can recognize the image 256 of the imaged layer. Based on the z-depth of the imaged layer, the surgeon can decide where to direct the cutting laser beam to form the capsulotomy cut 250. The cutting laser beam is typically scanned along the same scanning circle 254 to form a cut-cylinder 260-c with a depth-range Dcut, typically smaller than Dimage. This way the placement of the cut-cylinder 260-c benefits maximally from the information contained in the image 252, and in particular in the image 256 of the imaged layer. The capsulotomy cut 250 is formed where the cut-cylinder 260-c intersects the lens capsule 222. In practice, the cut cylinder

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260-c is often formed as a stack of bubble-circles, where the individual circles are created by directing the laser pulses along a circular scan-pattern at a fixed z-depth to cause photodisruption, followed by the formation of a similar circle at a slightly lesser z-depth.

In some typical cases, the image depth-range Dimage can be 5-10 millimeters, whereas the cut depth-range Dcut can be in the range of 50-200 microns, in some cases 75-150 microns, sometimes approximately 100 microns.

It is noted that the bubbles of the cut-cylinder 260-c can scatter and deflect laser pulses applied in subsequent surgical steps. For example, in a cataract surgery the capsulotomy can be followed by the lens fragmentation or lysis. The bubbles of the cut-cylinder 260-c can negatively impact the precision and efficiency of this subsequent lens-fragmentation by scattering the lens-fragmenting laser pulses.

Fortunately, when a z-axis of the lens 220 is parallel to a z-axis of the laser system 100, the depth range Dcut of the cut cylinder 260-c can be as little as 100 microns, creating only a limited number of bubbles. Thus, in the case of a well-aligned lens 220, the bubbles of the cut-cylinder 260-c introduce only a limited amount of scatter for the subsequent lens fragmentation laser pulses.

FIG. 4B illustrates, however, that in the typical surgical case the crystalline lens 220 can be tilted. This situation can occur for a variety of reasons. For example, the weight of the objective 134 can push the lens 220 sideways upon docking to the eye 1. Or, applying suction at the patient interface 136 to immobilize the eye 1 can lead to a tilting of the lens 220 as well.

FIG. 5B illustrates the image 252 of such a tilted lens 220 unfolded along the angular scanning variable of the scanning circle 254. In contrast to the non-tilted case of FIG. 5A, the image 256 of the tilted imaged layer can exhibit substantial sinusoidal oscillations. The amplitude of these oscillations can be as much as 300-500 microns. To make sure that the capsular bag 222 is cut everywhere along this sinusoid, the cut-cylinder 260-c can be formed with a much enlarged depth-range Dcut, exceeding the amplitude of the sinusoid. In the above example, Dcut can be 400-600 microns to be sure that the capsular bag 222 was cut along the entire sinusoid. Clearly, this approach may create 4-6 times more photodisrupted bubbles during capsulotomy than the procedure for a non-tilted lens. Capsulotomy bubbles in such an increased number can scatter the laser pulses of the subsequent lens fragmentation to a substantial degree, threatening its precision and efficacy.

FIGS. 6A-H illustrate that some implementations of the laser system 100 can substantially reduce the number of photodisrupted bubbles by generating bubbles only in a narrow proximity of the imaged layer.

As described above, this outcome can be achieved, for example, by the imaging-based laser-controller 120 imaging the capsular bag 222, controlling the scanning of the beam of laser pulses to the points of the scan-pattern, and controlling a laser-power parameter of the laser pulses according to the distance of the points of the scan-pattern from the imaged layer.

FIGS. 6A-B illustrate that as the laser pulses are directed to points of the scan-pattern, the laser controller 120 can modify or adjust a laser-power parameter of the pulses. In particular, when a laser pulse is directed to a point of the scan pattern that is within a Dcut distance from the image 256 of the imaged layer along the z axis, the laser-controller 120 can adjust its laser-power parameter to a high value, e.g. above a photodisruption threshold. Whereas, when a laser pulse is directed to a point of the scan pattern that is farther

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than Dcut from the image 256 of the imaged layer, the laser-controller 120 can adjust its laser-power parameter value to a low value, such as below a photodisruption threshold.

The just-described method creates bubbles only in a Dcut proximity of the imaged layer and therefore substantially reduces the number of bubbles to a value close to the number of bubbles for a well-aligned lens. For this reason, the scattering of the subsequent lens-fragmenting laser pulses by these capsulotomy bubbles is substantially reduced. Using the earlier value of Dcut being 400-600 microns for a tilted lens and 100 microns for a non-tilted lens, the present method may reduce the scattering of the lens-fragmenting bubbles by a factor of 4-6: a considerable gain in precision and control.

FIG. 6A illustrates the implementation when the scanning of the capsulotomy laser pulses of the scan-pattern is performed along the z-axis for fixed points of the circular scan. FIG. 6B illustrates the implementation when the scanning is performed along the circular scan with a fixed z-depth. This implementation can be used to create the above mentioned stacked circles. In either implementation, the points with high laser-power are placed within a tracking band 257 with a z-extent of Dcut.

FIGS. 6C-E illustrate the implementation when the laser pulses are scanned at fixed z-depths along the circular scan. A tracking band 257 can be defined as the set of points of the scan-pattern that are within the preselected distance Dcut from the image 256 of the imaged layer.

FIGS. 6D-E illustrate the laser power parameter of the pulses along the circular scan at two selected z-depths of 3600 microns and 3650 microns in an unfolded representation. The laser-controller 120 can control the laser power of the pulses that are directed to points inside the tracking band 257 to be above a photo-disruption threshold, and the laser power of the pulses that are directed to points outside the tracking band 257 to be below the photo-disruption threshold. In this embodiment, photodisrupted bubbles are only generated at points within the tracking band 257, achieving the above functionality of the laser system 100.

FIG. 6F expresses the same operation in a folded representation. Here the value of the laser power parameter is shown as a function of the angular scanning variable (typically the angle), projected on the scanning circle 254 itself. Again, for those points of the scan-pattern that lie within the tracking band 257, the laser power is high—indicated by a thick line—whereas for those points that lie outside the tracking band 257, the laser power is low.

FIGS. 6G-H illustrate a related implementation, where the laser-power controller 120 controls the laser power parameter as a function of the distance of the points from the imaged layer, wherein the laser-power is a decreasing function of the distance. FIG. 6G illustrates the implementation where this function is essentially a two-valued step-function. FIG. 6H illustrates the implementation where this function is a continuous function, its value decaying with the increasing distance from the imaged layer. In some implementations, it may be easier to control the laser power in the continuous manner of FIG. 6H.

The above-outlined implementations depend on the knowledge of the distance between the points of the scan-pattern and the imaged layer. Three stages are involved in determining this distance. First, the identity of the imaged layer is identified in the image 252 to determine the image 256 of the imaged layer. Then, the z-depth coordinate of the imaged layer is determined. Finally, the distance of the imaged layer and the points of the scan-pattern can be

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determined, for example, by taking the difference of the z-depth coordinates of the points of the scan-pattern and the imaged layer at the corresponding angular scanning coordinates, such as at the same angle.

Concerning the first step, the raw image 252 does not isolate or identify the imaged layer explicitly. Thus, establishing the identity of the imaged layer may necessitate an analysis of the image 252. As discussed earlier, this analysis of the image can be performed by the imaging system 122, the pattern generator 124, or the image analyzer 126, possibly assisted by an input from a system operator through the operator interface 128.

FIG. 7 illustrates that the imaging system 122 can support the identification of the imaged layer and the determination of its z-depth coordinates in different ways. In some implementations the laser system 100 can include the operator interface 128 and the imaging system 122 can support the identification of the imaged layer using an input from an operator through the operator interface 128.

For example, on a graphical user interface, or GUI, the operator interface 128 can prompt the operator to fit a model curve 258 to the spots in the image 252 representing the imaged layer. Since in the case of a tilted ellipsoid-shaped lens the image 256 of the imaged layer is typically a sinusoidal curve, the operator interface 128 can display a generic sinusoidal curve 258 on the GUI and prompt the operator to fit this model curve 258 to the layer-spots in the image 252. Once the operator fitted the model curve 258 to the layer-spots in the image 252, the model curve 258 can serve as the image 256 of the imaged layer.

The operator can achieve this task through various approaches: by shifting the model curve 258 by an Xshift in the X direction (i.e. adjusting the angle along the circular scan) and by shifting the model curve 258 by a Yshift in the Y direction (i.e. adjusting the z-depth coordinate). In other implementations the operator can be prompted to adjust the scale of the model curve 258 to the scale of the sinusoidally located layer-spots in the image 252, i.e. to rescale the z-depth of the model curve 258 to fit the z-depth of the layer-spots. Many other fitting techniques can be implemented to achieve analogous functionalities.

The operator interface 128 can receive the input from the operator in many different ways, including through a keyboard, a touch-screen, a computer-communication channel, an external memory, a flash-drive, an internet connection, a speech-recognition apparatus or a wireless connection.

In other implementations, the determination of the identity and the z-depth of the imaged layer can be performed by the laser system 100 without the input of a surgeon or operator. In particular, the imaging system 122 can be configured to determine the identity and then the z-depth coordinate of the imaged layer by a processor or micro-computer performing a feature-recognition analysis of the image 252. For example, the imaging system 122 can determine the identity and coordinates of the imaged layer by locating local maxima of the gradient of the spot intensity. In other implementations, an edge-recognition algorithm can be used. In these implementations, the imaging system 122 can identify the manifold of the maximum-gradient points as the image 256 of the imaged layer without resorting to fitting a model curve 258. In some implementations, of course, the imaging system 122 can make use of a model curve 258 to identify the image 256 of the imaged layer.

In the above implementations, once the identity of the imaged layer has been determined in the image 252, the z-depth coordinates of the imaged layer can be determined

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in a straightforward manner, for example, by counting the pixels in the image 252, or using a reference or a look-up table.

For the image analysis, the imaging system 122 can utilize a result of a pre-surgery measurement, statistical data, video image data, ophthalmic coherence tomography image data, or a model-based computation during the determination of the z-depth.

Once the z-depth of the imaged layer has been determined, the imaging system 122 can forward the z-depth and the corresponding scanning coordinates of the imaged layer to the pattern generator 124 to carry out the last stage, the determination of the distance between the imaged layer and the points of the scan-pattern, generated by the pattern generator 124. This stage can be carried out, for example, by subtracting the z-depth coordinates of the points of the scan-pattern from the z-depth coordinates of the imaged layer that correspond to the same scanning variable, such as the same scanning angle.

Finally, having determined the distance of the points of the scan-pattern from the imaged layer, the pattern generator 124 can associate a laser-power parameter above a photodisruption threshold with those points that are closer to the imaged layer than a predetermined distance, and associate a laser-power parameter below a photodisruption threshold with those points that are farther from the imaged layer than the predetermined distance, as described in relation to FIGS. 6A-H.

In some implementations, the imaging system 122 only captures the image 252 but does not identify the imaged layer or determine its z-depth coordinates. In these embodiments, the imaging system 122 can simply forward the unprocessed image 252 to the pattern generator 124 without analyzing it. The pattern generator 124 can receive the image 252, identify the imaged layer and determine the z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image scan.

As above, in some implementations, the pattern generator 124 can determine the z-depth of the imaged layer by performing a feature-recognition analysis of the received image 252. In other implementations, the pattern generator 124 can receive an operator input through the operator interface 128 during the process of determining the z-depth of the imaged layer, as described before.

In these implementations, once the z-depth coordinates of the imaged layer have been determined, the pattern generator 124 can define a tracking band 257 as a manifold of the points of the scan-pattern that are within a predefined distance from the coordinates of the imaged layer. Then the pattern generator 124 can associate a laser-power parameter above a photodisruption threshold with points of the scan-pattern inside the tracking band 257, and a laser-power parameter below a photodisruption threshold with points of the scan-pattern outside the tracking band 257.

Yet other implementations of the laser controller 120 may include an image analyzer 126 that can determine the z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image-scan. As was illustrated in FIGS. 3B-D, the image analyzer 126 can be self-standing or at least partially integrated with the imaging system 122 or the pattern generator 124.

The image analyzer 126 can identify the imaged layer and determine the z-depth coordinate of the imaged layer by performing a feature-recognition analysis of the image 252. In other implementations, the image analyzer 126 can determine the z-depth coordinate by making use of an operator input through an operator-interface 128.

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The operation of the laser system 100 can be demonstrated on the example of the capsulotomy procedure, where the imaged layer is the lens capsule 222 between the lens 220 and the aqueous anterior chamber 230. In this case, the scan-pattern corresponds to the cut-cylinder 260-c intersecting the lens capsule 222 at the capsulotomy cut 250. The pattern generator 124 can associate a photodisruptive laser-power parameter with points inside a tracking band 257 related to the intersection 250 of the cut-cylinder 260-c and the lens capsule 222, and a non-photodisruptive laser-power parameter with points outside the tracking band 257.

FIG. 8A illustrates a first cataract procedure 300 performed without the benefits of the laser system 100. The cataract procedure 300 can be practiced when the capsulotomy generates an excessive number of bubbles as in FIGS. 4B-5B. To prevent excessive scattering by these capsulotomy bubbles, the lens fragmentation is performed prior to the capsulotomy. In detail, the cataract procedure 300 can include a first imaging 310 of the capsule 222, performed by an OCT procedure, followed by a lens fragmentation 320. During the lens fragmentation 320 the capsule 222 expands because of the large number of bubbles generated in the crystalline lens 220. The fragments of the lens 220 are removed through an opening, cut into the capsule 222 by a capsulotomy 340. However, since the capsule 222 has expanded during the lens fragmentation 320, the results of the first imaging 310 are not reliable anymore. Therefore, the capsulotomy 340 has to be preceded by a second imaging 330. The second imaging 330 can take up precious surgical time and increase the discomfort of the patient. Both of these factors can endanger the efficacy of the cataract procedure 300.

FIG. 8B illustrates a cataract procedure 350 with an embodiment of the laser system 100. Since the laser system 100 is capable of creating only a limited number of bubbles during the capsulotomy, the capsulotomy can be performed before the lens fragmentation. This change of sequence can reduce the surgical time to a considerable degree and thus increase the precision of the cataract procedure substantially.

In some detail, the cataract procedure 350 can include an imaging 360 of the capsule 222, e.g. by an OCT imaging system, followed by a capsulotomy 370, and completed by a lens fragmentation 380. Since the capsulotomy 370 does not deform the lens 220, there is no need for a second imaging, in contrast to the procedure 300.

FIG. 9 illustrates an imaging-controlled cataract method 400 in more detail. The method 400 can include an imaging 410 of an imaged ophthalmic layer in an imaged region of an eye, followed by an identifying 420 of the coordinates of the imaged layer from the image. These tasks can be performed, for example, by the imaging system 122 of the imaging-based laser-controller 120. The identifying 420 can include performing a feature-recognition analysis. In other cases, it can include receiving an operator-input through an operator interface 128. These tasks can be performed by the imaging system 122, the pattern generator 124 or the image analyzer 126.

Next, the method 400 can include a generating 430 of coordinates of points of a scan-pattern, and a determining 440 of a distance of the points of the scan-pattern from the imaged layer. These steps can be performed for example, by the pattern generator 124.

The method 400 can further include an associating 450 of laser-power parameters with the generated points based on their determined distance. The tasks 420 to 450 can include receiving possible inputs 422-452 from an operator of the laser system 100 through the operator interface 128.

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The method can also include a signaling 460 of the generated coordinates of the points of the scan-pattern to the beam scanner 116 and a signaling 470 of the corresponding laser-power parameters to the beam attenuator 114.

FIG. 10 illustrates the case of surgical relevance when the lens capsule 222 has an uneven shape. This situation can arise in different circumstances. For example, the docking of the patient interface 136 can cause considerable deformation of the anterior segment of the eye 1. Or an ophthalmic trauma or a prior lens fragmentation procedure can result in an uneven lens shape. In any of these circumstances, the laser system 100 can be capable of analyzing an image 256 of the imaged layer that exhibits more than two local extrema. Visibly, a simple sinusoidal model curve 258 is insufficient to identify the imaged layer and to determine its z-depth coordinate in this case. Therefore, embodiments of the imaging system 122, the pattern generator 124 or the image analyzer 126 can be capable of recognizing the imaged layer and determine its z-depth coordinate even in this more challenging case, for example, by using sophisticated feature-recognition software. Having determined and characterized the image 256 of the imaged layer can allow the pattern generator 124 to define the tracking band 257 to associate laser-power parameters with the spots of the scan-pattern accordingly.

FIGS. 11A-D illustrate that the imaging system 122 of the laser system 100 can image a region in the eye, the pattern generator 124 can generate coordinates of points of a scan-pattern for the beam scanner 116, and associate a laser-power parameter with the points of the scan-pattern depending on a distance of the points from a target-pattern.

An example for such a target pattern can be a chop pattern 500, including the chop-planes 500-X and 500-Y. Such chop patterns 500 can be used for lens fragmentation. FIG. 11A illustrates the case when the z-axis of the lens 220 is aligned with the z-axis of the laser system 100. In this case the chop-planes 500-X and 500-Y are also parallel to the z-axis of the laser system 100.

FIG. 11B illustrates that if the lens 220 is tilted relative to the z-axis of the laser system 100, as illustrated e.g. in FIG. 4B, then the chop planes 500-Xt and 500-Yt can be tilted as well. Since the scan-pattern often includes a first manifold of points at a first fixed z-depth, followed by a second manifold 45 at a slightly lesser z-depth, the scan-pattern of tilted chop-planes with laser systems that cannot adjust the power of the laser pulses would create cuts into the capsular bag 222, leading to massive surgical complications.

In contrast, embodiments of the laser system 100 can 50 associate laser-parameters depending on the distance of the points of the scan-pattern from the chop planes 500-Xt and 500-Yt.

FIGS. 11C-D illustrate the points of the scan-pattern with low and high laser power, generated by the pattern generator 55 124 to form the tilted 500-Xt and 500-Yt chop planes. Visibly, creating cuts by adjusting the power of the laser pulses depending on their proximity to the target-pattern can avoid cutting into the capsular bag—a major surgical advantage.

FIG. 11D illustrates clearly that, as it was the case of the tracking band 257, a photodisruptive laser-power parameter can be associated with scan-points that are closer to the target-pattern 500-Xt and 500-Yt than a predetermined distance Dcut, and a non-photodisruptive laser-power parameter with the scan-points that are farther from the target-pattern than the predetermined distance Dcut.

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In other implementations, the cutting surface can be a circular surface-segment, a spiral surface-segment, a corneal access cut and a limbal relaxing cut.

FIGS. 12A-B illustrate that in some cases the target pattern 260-2 can be a target volume with an axis tilted relative to an optical axis of the laser system 100. Here, the scan pattern includes cylindrical patterns 260-1, and the laser-power parameter of the points of this scan-pattern is adjusted to form a tilted volume cut 260-2. Such a utility can 10 be useful for correcting a refractive property of the lens 220, for example.

In some implementations, the pattern generator 124 can be configured to associate the laser-power parameters with the points of the scan-pattern depending additionally on a 15 distance of the points from an ophthalmic layer, imaged by the imaging system 122.

While this specification contains many specifics, these should not be construed as limitations on the scope of the invention or of what can be claimed, but rather as descriptions of features specific to particular embodiments. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features can be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination can be directed to a subcombination or variation of a subcombination.

The invention claimed is:

1. An imaging-based laser system, comprising:
 - a laser-beam system, including:
 - a laser engine, configured to generate a beam of laser pulses,
 - a beam attenuator, configured to modify a laser-power parameter of the laser pulses, wherein the laser-power parameter is one of a pulse energy, a pulse power, a pulse length and a pulse repetition rate, and
 - a beam scanner, configured to scan the beam to points of a cylindrical scan-pattern in an eye; and
 - an imaging-based laser-controller, configured to:
 - image a layer in the eye that is tilted relative to an optical axis of the laser system,
 - determine z-depths of a sequence of points in the cylindrical scan-pattern that correspond to the imaged layer in the eye,
 - generate a tracking band within the cylindrical scan pattern defining a cut to be made in the eye, wherein a lower boundary of the tracking band has a non-uniform z-depth that varies according to the determined z-depths of the sequence of points corresponding to the imaged layer,
 - cause the beam scanner to scan the beam of laser pulses to the points of the cylindrical scan-pattern, and
 - cause the beam attenuator to control the laser-power parameter of the laser pulses such that a laser power parameter of laser pulses in the tracking band is above a photo-disruption threshold, and a laser power parameter of laser pulses outside the tracking band is below the photo-disruption threshold.
2. The laser system of claim 1, the beam attenuator comprising at least one of:

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a Pockels cell, a polarizer-assembly, a mechanical shutter, an electro-mechanical shutter, and an energy wheel.

3. The laser system of claim 1, wherein:

the beam attenuator is disposed between the laser engine and the beam scanner in a path of the beam. 5

4. The laser system of claim 1, wherein:

the beam attenuator is disposed after the beam scanner in a path of the beam. 10

5. The laser system of claim 1, wherein:

the beam attenuator is part of the laser engine. 15

6. The laser system of claim 1, wherein:

the beam attenuator and the beam scanner are at least partially integrated. 20

7. The laser system of claim 1, the laser-controller comprising:

an imaging system, configured to image the imaged layer in the eye; and 25

a pattern generator, configured to:

generate coordinates of each point within the cylindrical scan-pattern, 30

associate a particular laser-power parameter with each point in the cylindrical scan pattern based on the tracking band, and

signal the generated coordinates of each point to the beam scanner, and 35

signal the particular laser-power parameter of each point to the beam attenuator. 40

8. The laser system of claim 7, the imaging system comprising:

at least one of an ophthalmic coherence tomography system, a Scheimpflug imaging system, a scanning imaging system, a single shot imaging system, an ultrasound imaging system, and a video imaging system. 45

9. The laser system of claim 7, wherein:

the imaging system is configured to image the imaged layer in an image region, wherein the image region is based on one of a loop, an arc, a line, and a two-dimensional pattern transverse to an axis of the imaging system, and 40

extends to an image depth along the axis of the imaging system. 45

10. The laser system of claim 7, wherein:

the imaging system is configured to support a determination of a z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image scan. 50

11. The laser system of claim 10, wherein:

the laser system comprises an operator interface; and the imaging system is configured to support the determination of the z depth coordinate of the imaged layer using an input from an operator through the operator interface. 55

12. The laser system of claim 11, wherein:

the operator interface is configured to assist the operator to fit a model curve to the image of the imaged layer. 60

13. The laser system of claim 11, wherein:

the operator interface is capable of receiving the operator input from at least one of a keyboard, a touch-screen, a computer-communication channel, an external memory, a flash-drive, an internet connection, a speech-recognition apparatus and a wireless connection. 65

14. The laser system of claim 10, wherein:

the imaging system is configured to determine the z-depth coordinate of the imaged layer by performing a feature-recognition analysis of the image of the imaged layer. 70

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15. The laser system of claim 14, wherein:

the imaging system is configured to utilize at least one of a result of a pre-surgery measurement, statistical data, video image data, ophthalmic coherence tomography image data,

and a model-based computation during the determination of the z-depth. 75

16. The laser system of claim 10, wherein:

the imaging system is configured to forward the z-depth and scanning coordinates of the imaged layer to the pattern generator; and

the pattern generator is configured

to determine the distance of the points of the scan-pattern from the imaged layer based on the forwarded coordinates of the imaged layer and the generated coordinates of the points,

to associate a first laser-power parameter above a photodisruption threshold with a first set of points closer to the imaged layer than a predetermined distance, and

to associate a second laser-power parameter below a photodisruption threshold with a second set of points farther from the imaged layer than the predetermined distance. 75

17. The laser system of claim 10, wherein:

the imaging system is configured to forward the z-depth and scanning coordinates of the imaged layer to the pattern generator; and

the pattern generator is configured

to determine the distance of the points of the scan-pattern from the imaged layer based on the forwarded coordinates of the imaged layer and the generated coordinates of the points, and

to associate with the coordinates of the points a laser-power parameter that is a decreasing function of the distance of the points from the imaged layer. 80

18. The laser system of claim 7, wherein:

the imaging system is configured to forward the image of the imaged layer to the pattern generator; and the pattern generator is configured

to receive the image from the imaging system, and to determine a z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image scan. 85

19. The laser system of claim 18, wherein:

the pattern generator is configured to determine the z-depth of the imaged layer in part by performing a feature-recognition analysis of the received image of the imaged layer. 90

20. The laser system of claim 18, wherein:

the pattern generator is configured to receive an operator input through an operator interface during the process of determining the z-depth of the imaged layer. 95

21. The laser system of claim 20, wherein:

the operator interface is capable of receiving the operator input from at least one of a keyboard, a touch-screen, a computer-communication channel, an external memory, a flash-drive, an internet connection, a speech-recognition apparatus and a wireless connection. 100

22. The laser system of claim 18, wherein:

the pattern generator is configured to:

generate the tracking band as a manifold of points within a predefined distance from the coordinates of the imaged layer; 105

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associate a laser-power parameter above a photodisruption threshold with points of the scan-pattern inside the tracking band, and

to associate a laser-power parameter below a photodisruption threshold with points of the scan-pattern outside the tracking band. 5

23. The laser system of claim **7**, the laser controller comprising:

an image analyzer, configured to determine a z-depth coordinate of the imaged layer corresponding to a scanning coordinate along an image-scan. 10

24. The laser system of claim **23**, wherein:
the image analyzer is configured to determine the z-depth coordinate of the imaged layer by performing a feature-recognition analysis of the image of the imaged layer. 15

25. The laser system of claim **23**, wherein:
the image analyzer is configured to determine the z-depth coordinate of the imaged layer by receiving an operator input through an operator-interface. 20

26. The laser system of claim **23**, wherein:
the image analyzer is at least partially integrated with one of the imaging system and the pattern generator. 25

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27. The laser system of claim **1**, wherein:
the imaged layer is a lens capsule between a lens of an eye and an aqueous anterior chamber of the eye;
the scan-pattern corresponds to a cylindrical capsulotomy cut intersecting the lens capsule; and
the imaging-based laser controller is configured to:

associate a photodisruptive laser-power parameter with points inside a tracking band related to the intersection of the cylindrical capsulotomy cut and the lens capsule, and

associate a non-photodisruptive laser-power parameter with points outside the tracking band.

28. The laser system of claim **27**, wherein:
the laser system is configured to perform a capsulotomy before a lens fragmentation during a cataract procedure.

29. The laser system of claim **27**, wherein:
the imaging-based laser controller is configured to analyze an image of the capsule boundary layer with more than two local extrema by at least one of a pattern generator and an image analyzer.

* * * * *

EXHIBIT 5



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(12) **United States Patent**
Kurtz et al.

(10) **Patent No.:** US 9,456,925 B2
(45) **Date of Patent:** Oct. 4, 2016

(54) **PHOTODISRUPTIVE LASER TREATMENT OF THE CRYSTALLINE LENS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1198 days.

(21) Appl. No.: **12/343,418**

(22) Filed: **Dec. 23, 2008**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**

A61F 9/008 (2006.01)

A61F 9/009 (2006.01)

(52) **U.S. Cl.**

CPC *A61F 9/008* (2013.01); *A61F 9/00838* (2013.01); *A61F 9/009* (2013.01); *A61F 2009/0087* (2013.01);

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(58) **Field of Classification Search**

CPC A61B 18/18; A61B 8/00; G01B 9/02

USPC 606/6, 5, 8, 10, 4; 600/439; 356/450

See application file for complete search history.

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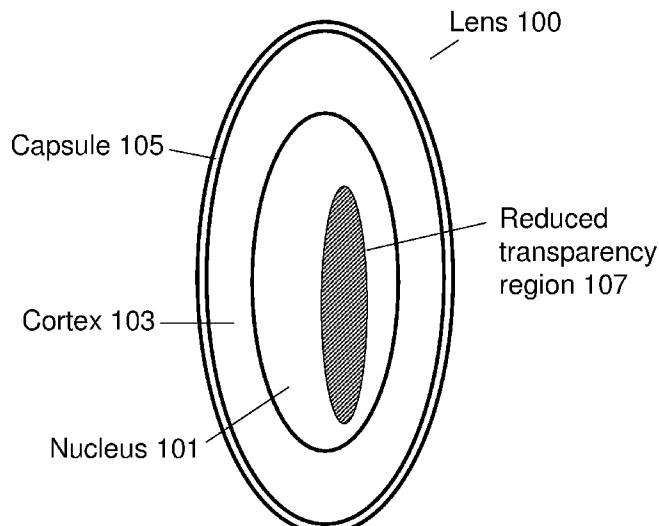
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(57)

ABSTRACT

Apparatus and methods of treating a hard lens region of an eye with a laser where one method includes identifying a boundary of the hard lens region, selecting a laser-parameter to enable a photodisruptive procedure in the hard lens region and to control a spreading of bubbles in the hard lens region, modifying a mechanical property of a posterior portion of the hard lens region in a proximity of the identified boundary by the photodisruptive procedure, and modifying a mechanical property of a portion anterior to the modified posterior portion of the hard lens region by the photodisruptive procedure. The laser bubbles can be applied to form incisions which are non transverse to an axis of the eye and intersect the lens fibers.

27 Claims, 31 Drawing Sheets



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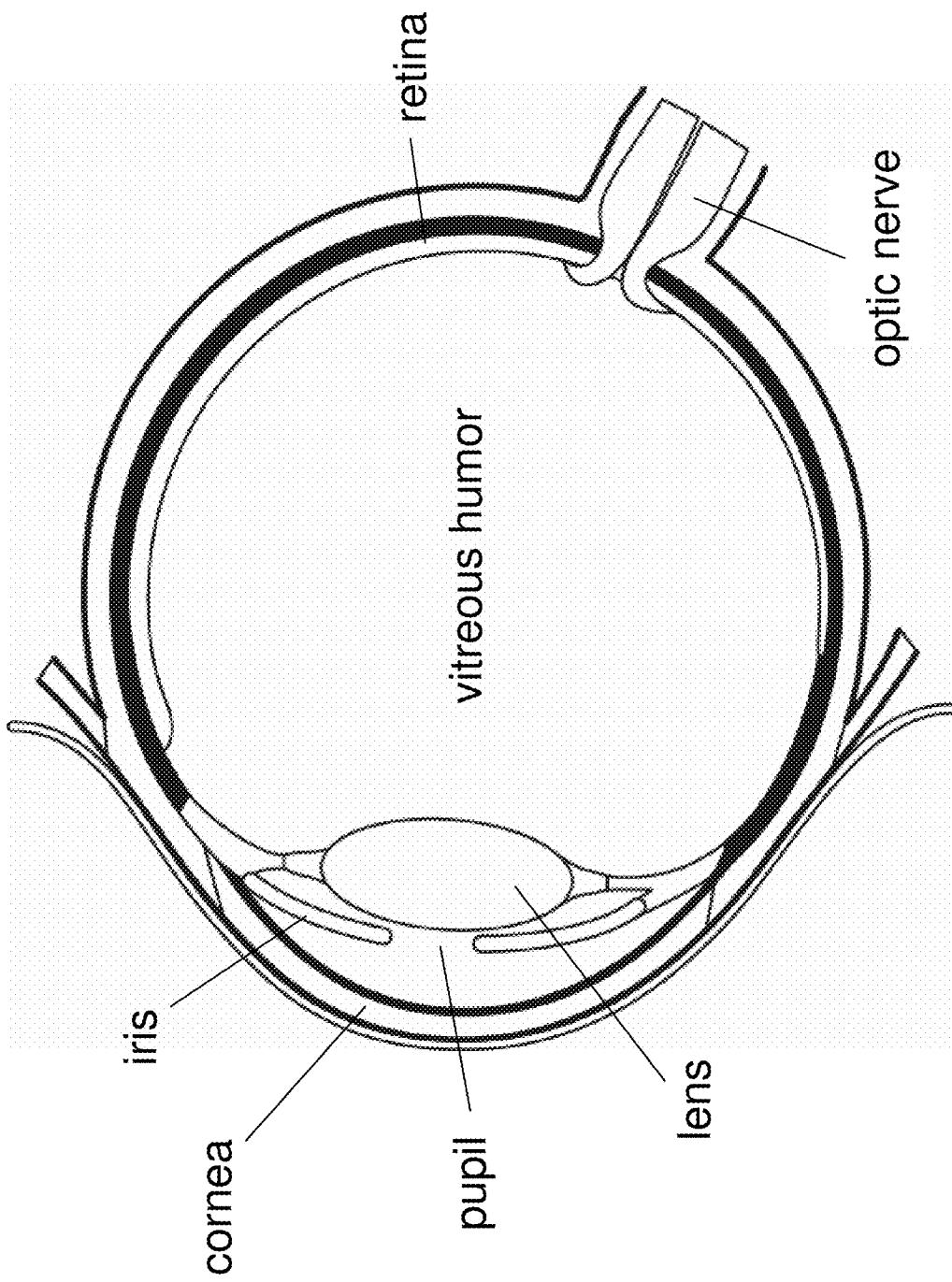


FIG. 1

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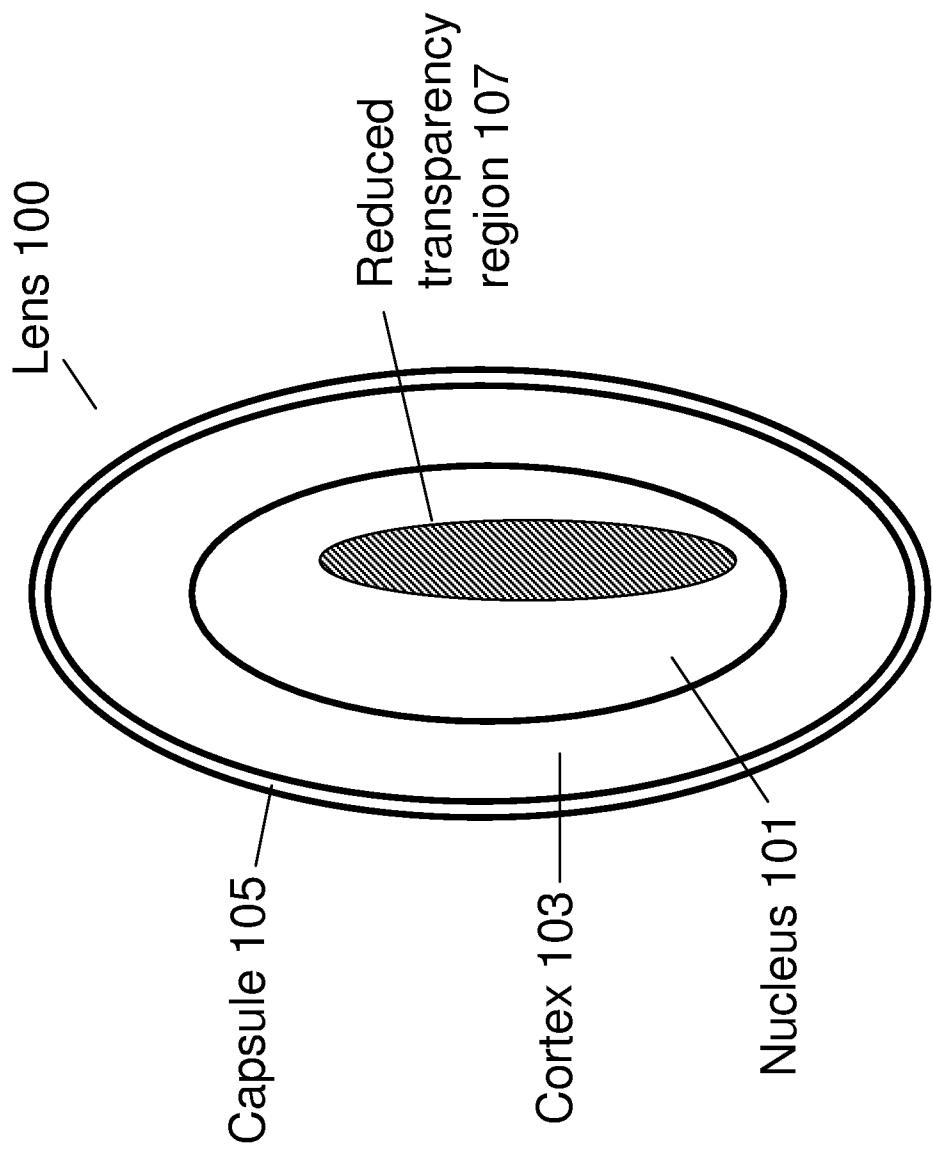


FIG. 2

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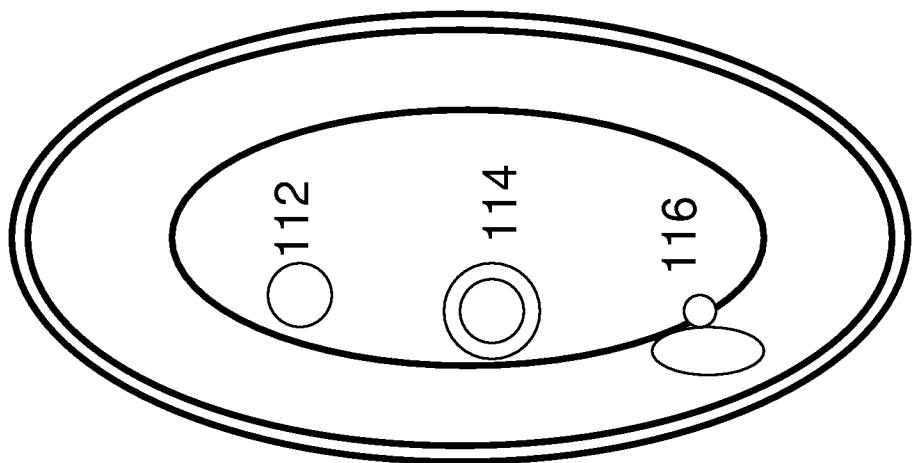


FIG. 3B

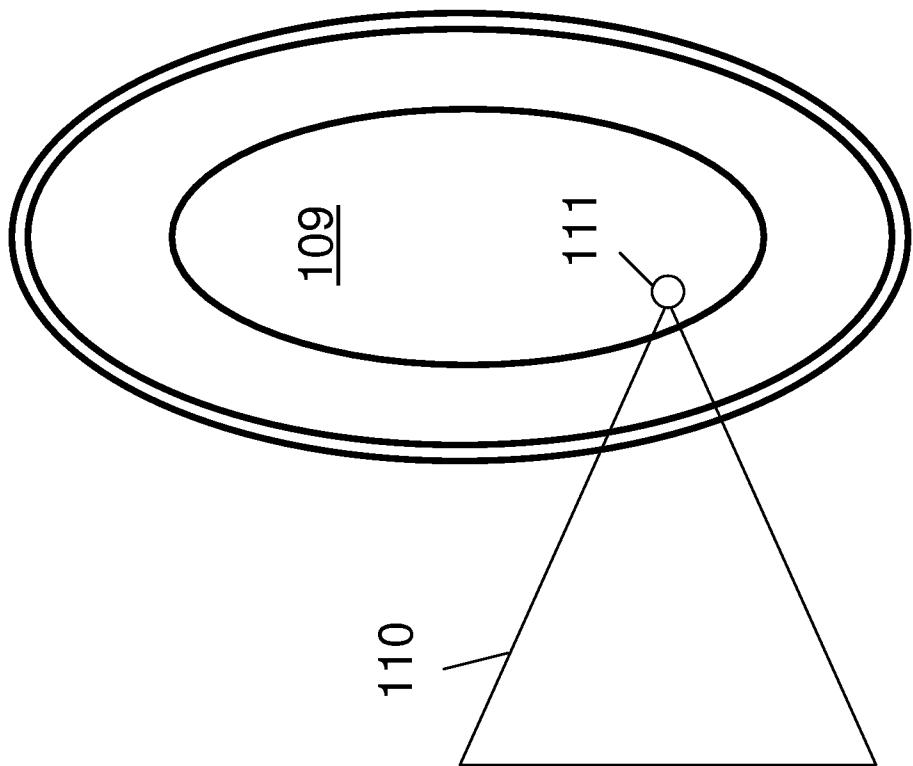


FIG. 3A

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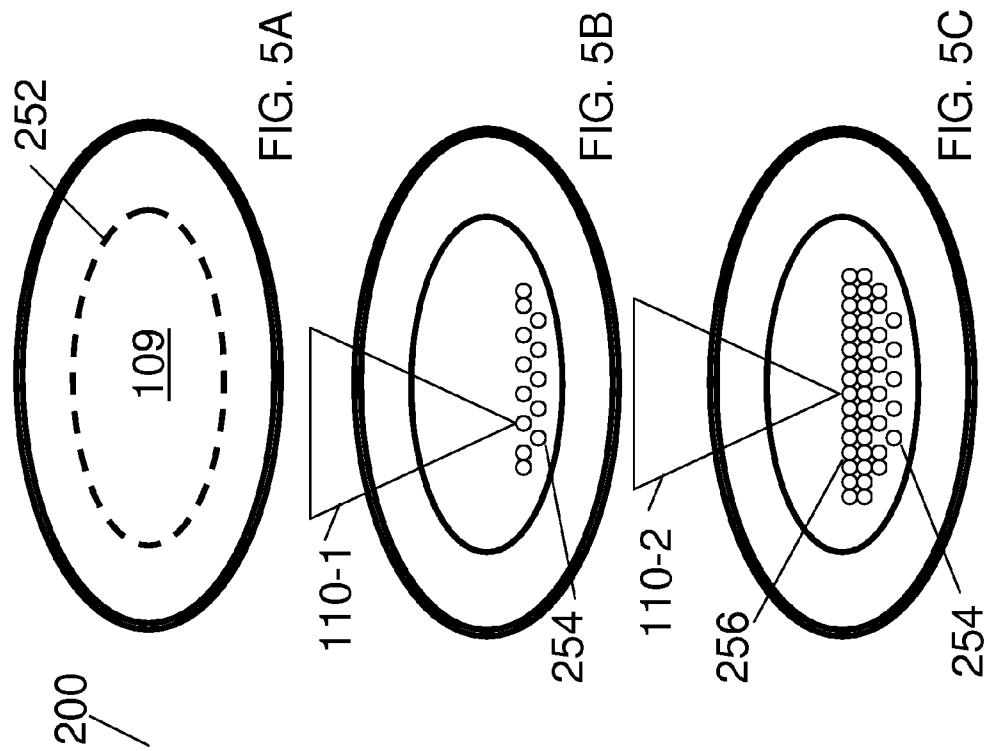
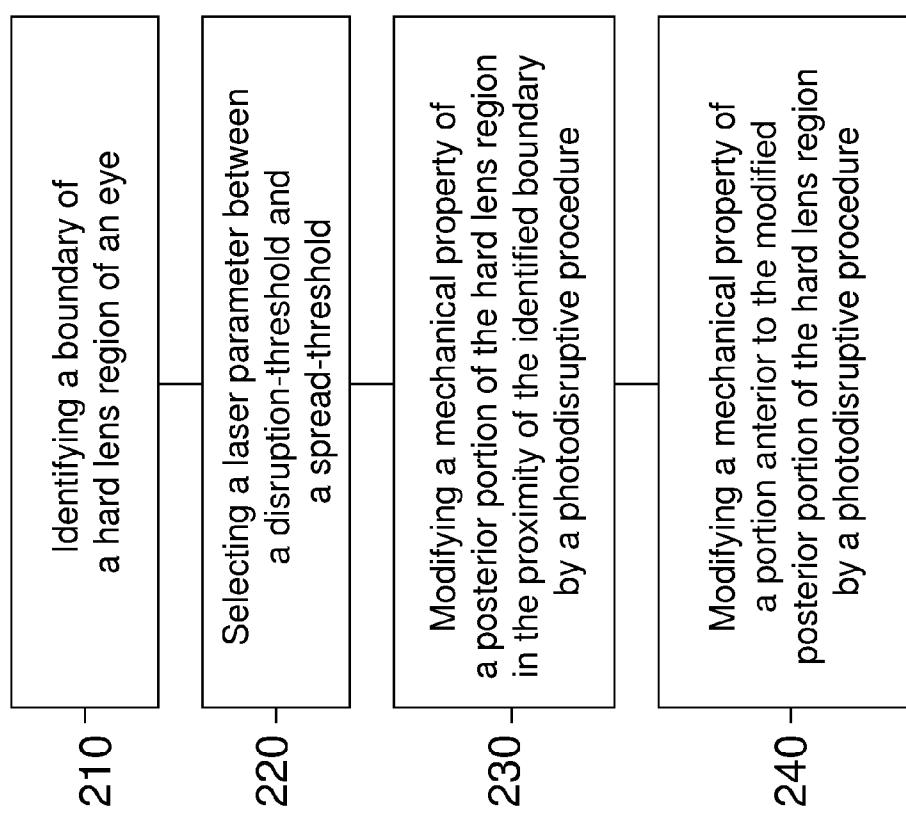


FIG. 5



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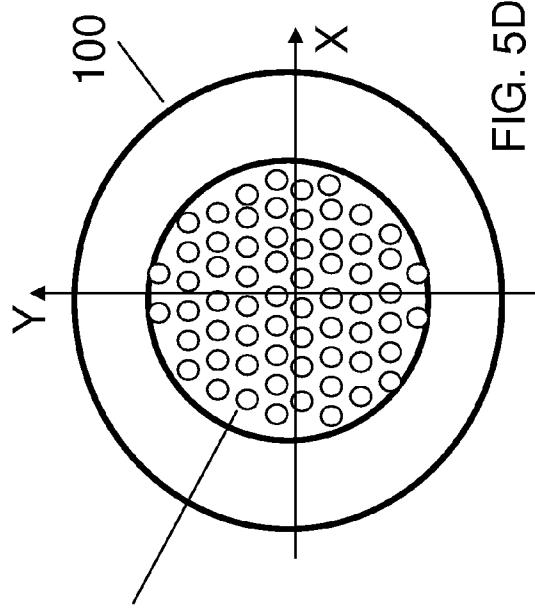


FIG. 5D'

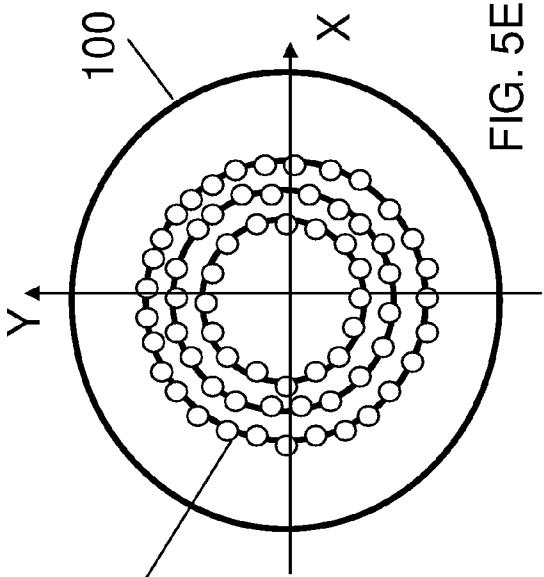


FIG. 5E'

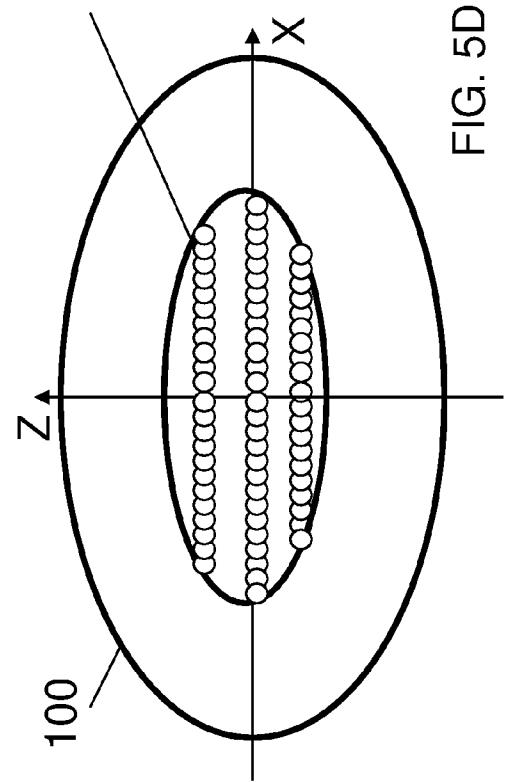


FIG. 5D

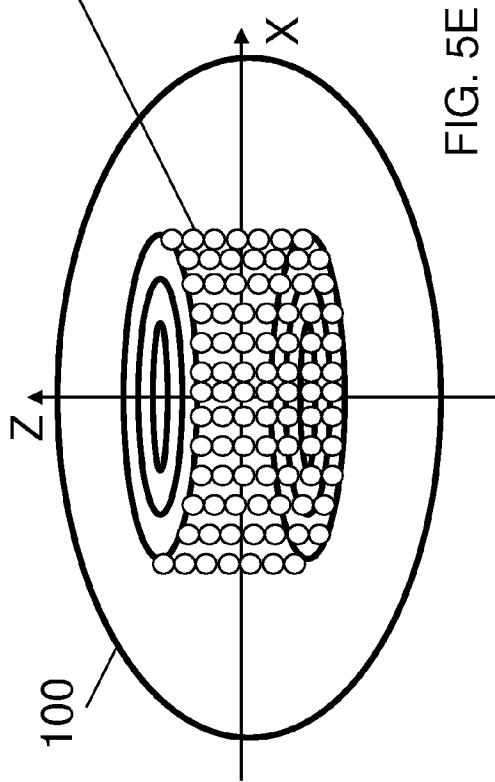


FIG. 5E

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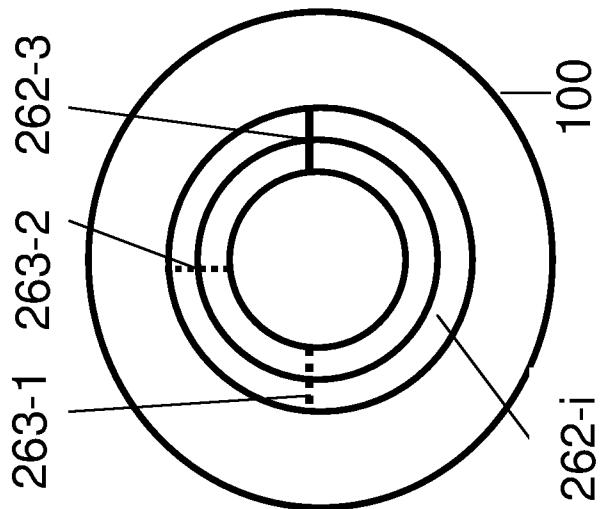


FIG. 5F''

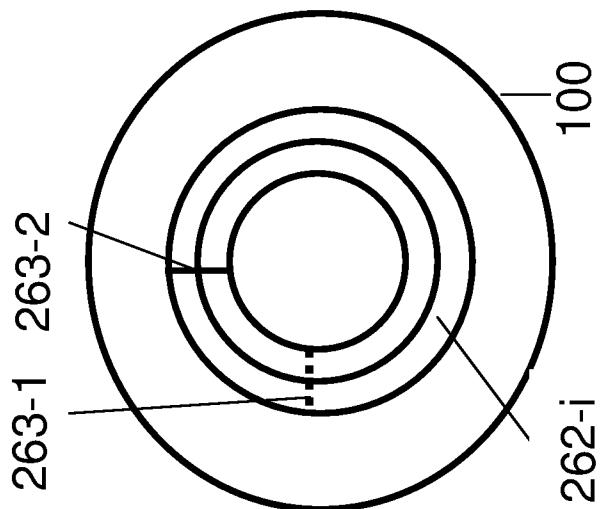


FIG. 5F'

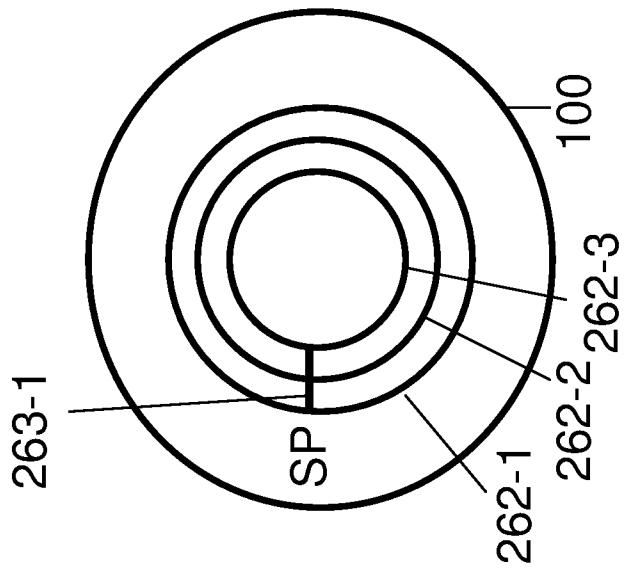


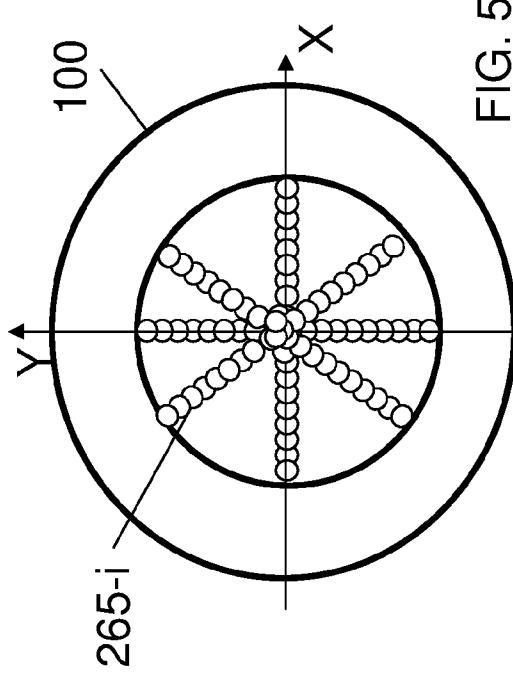
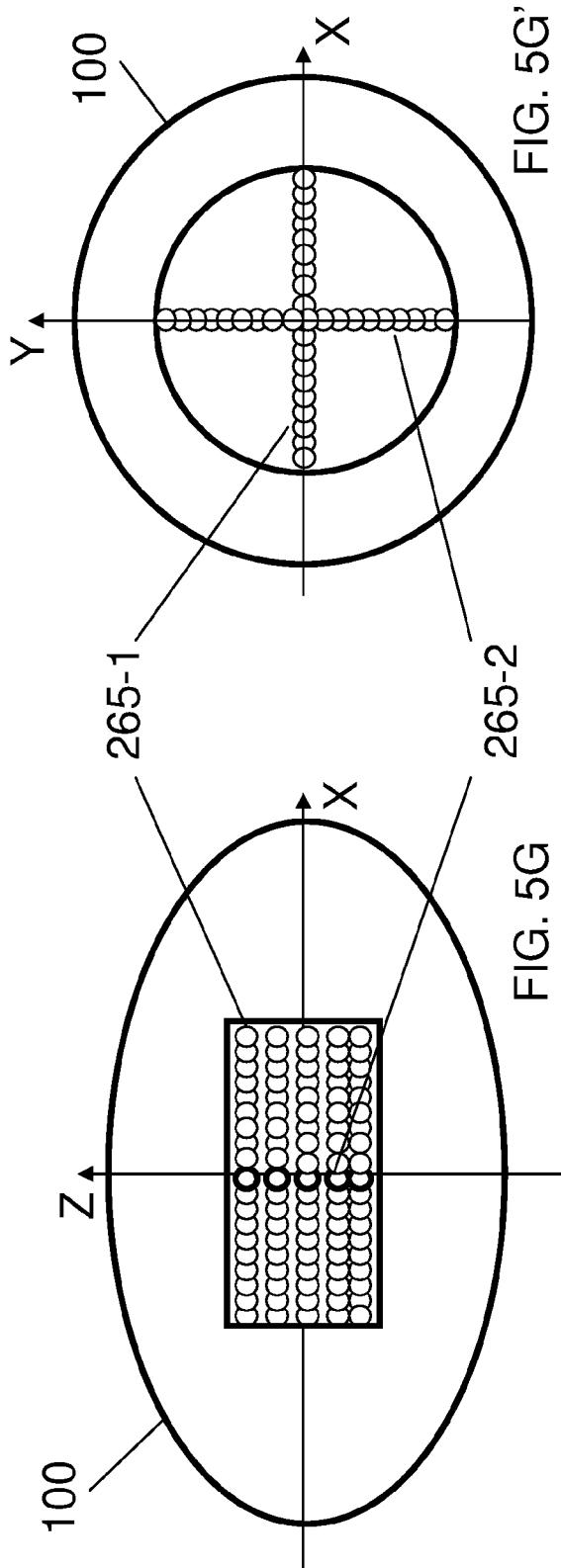
FIG. 5F

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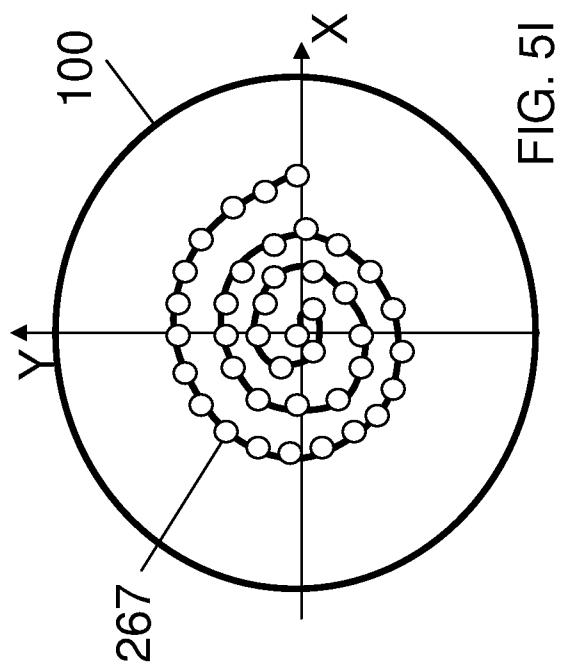
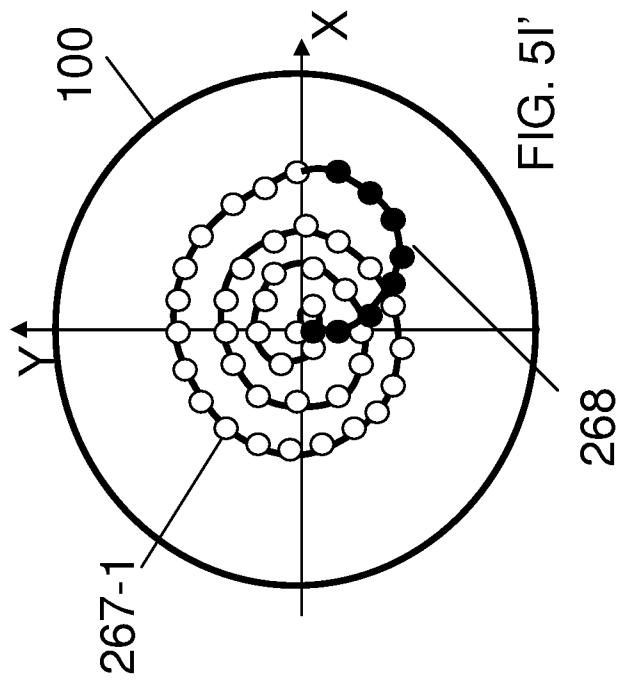


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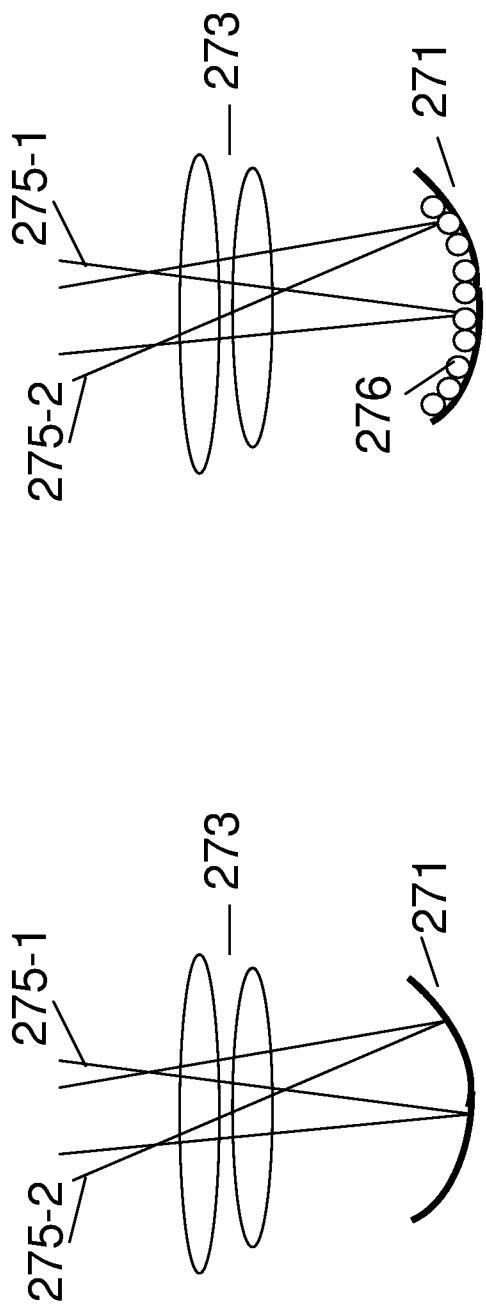


FIG. 5J'
FIG. 5J

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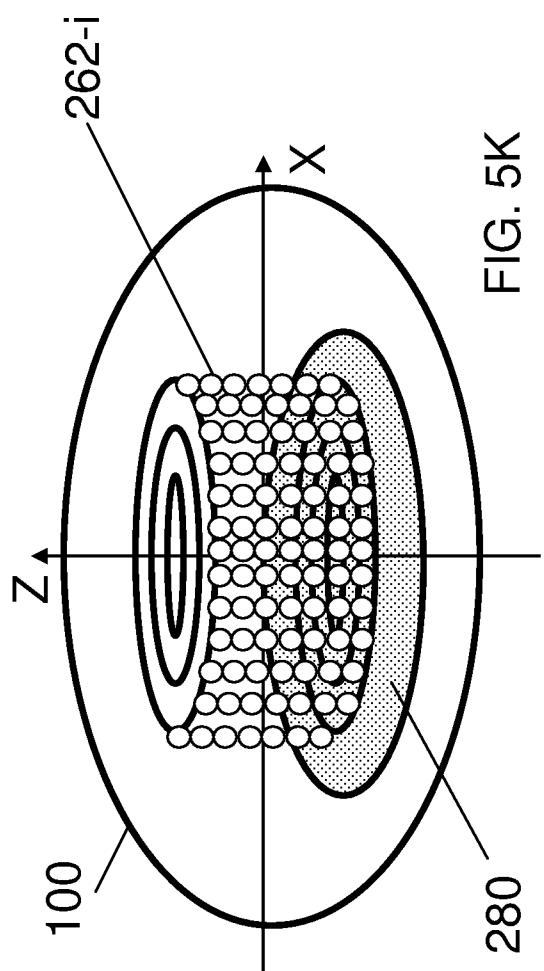


FIG. 5K

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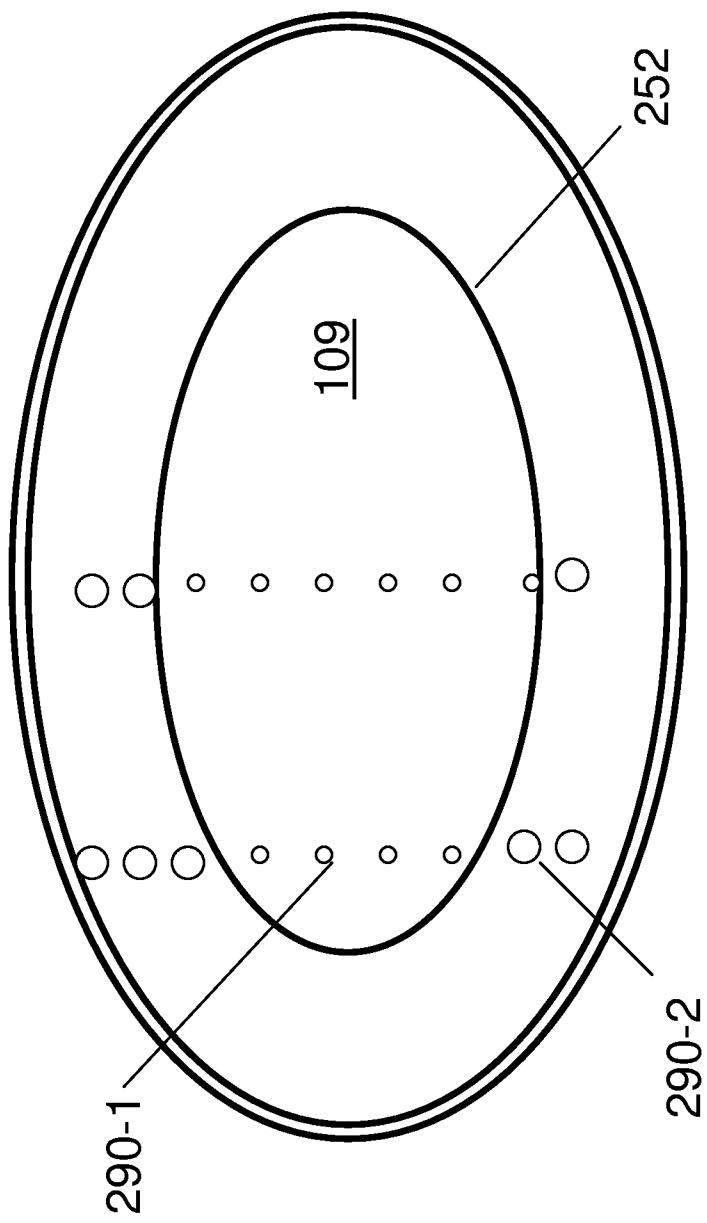


FIG. 6

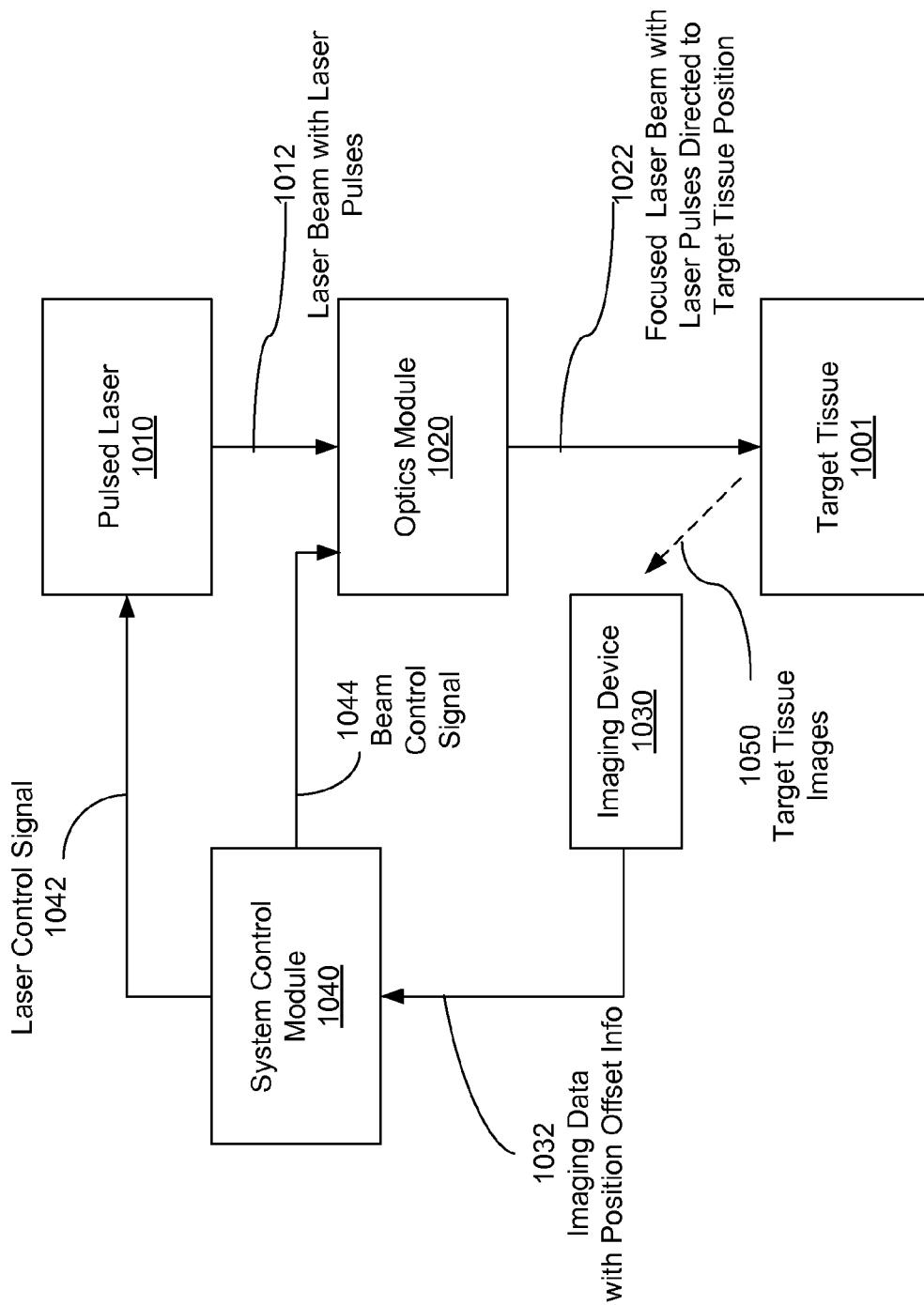
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F/G. 7



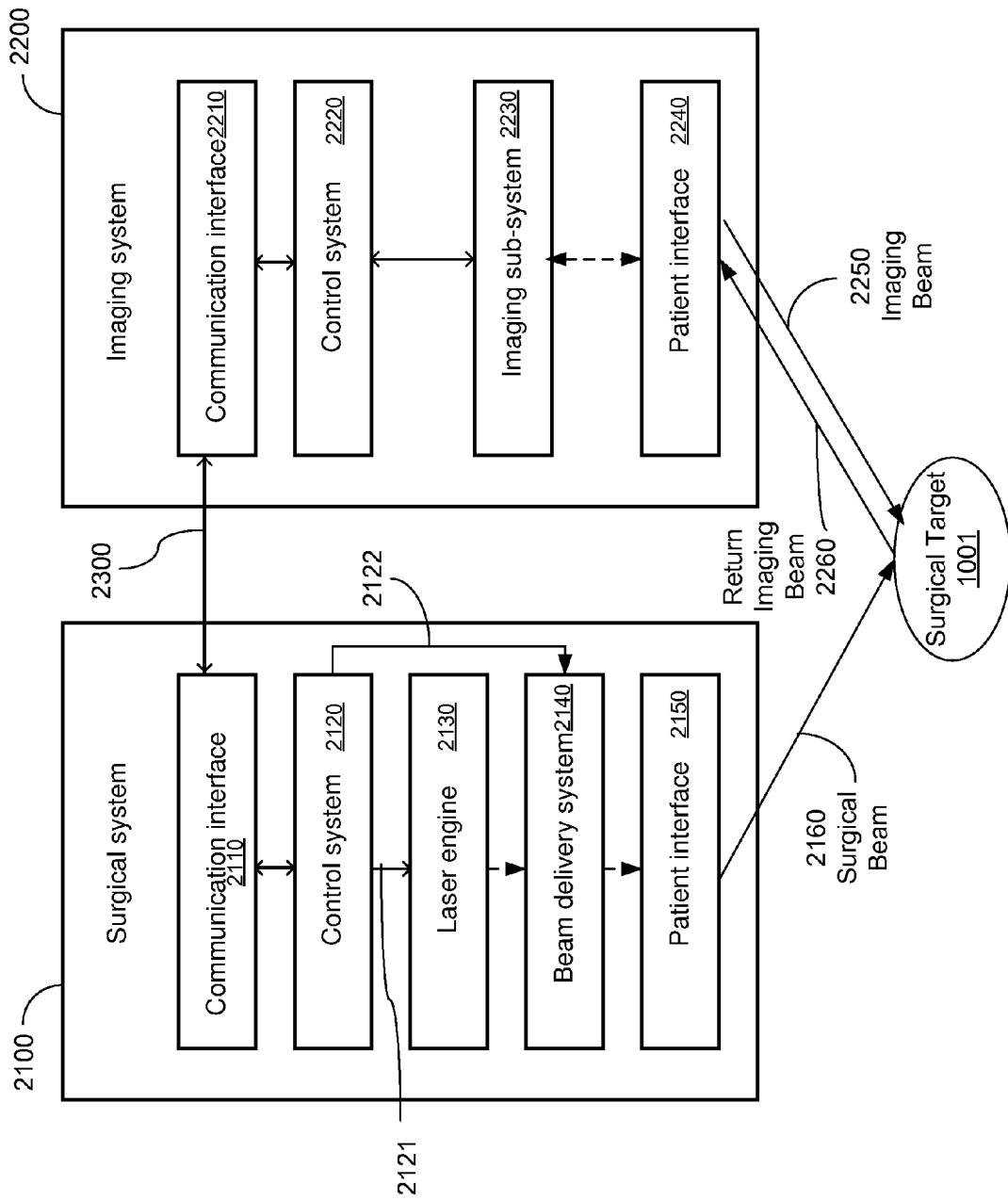
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FIG. 8



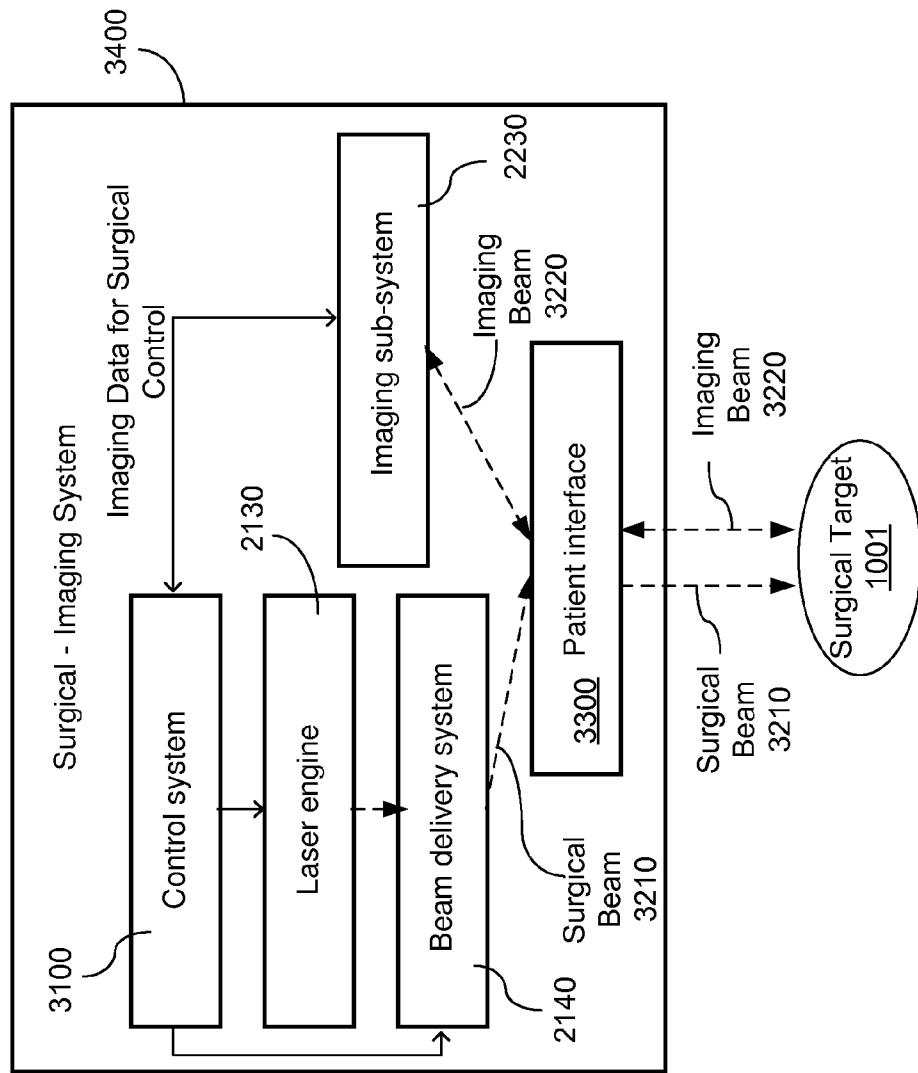
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FIG. 9



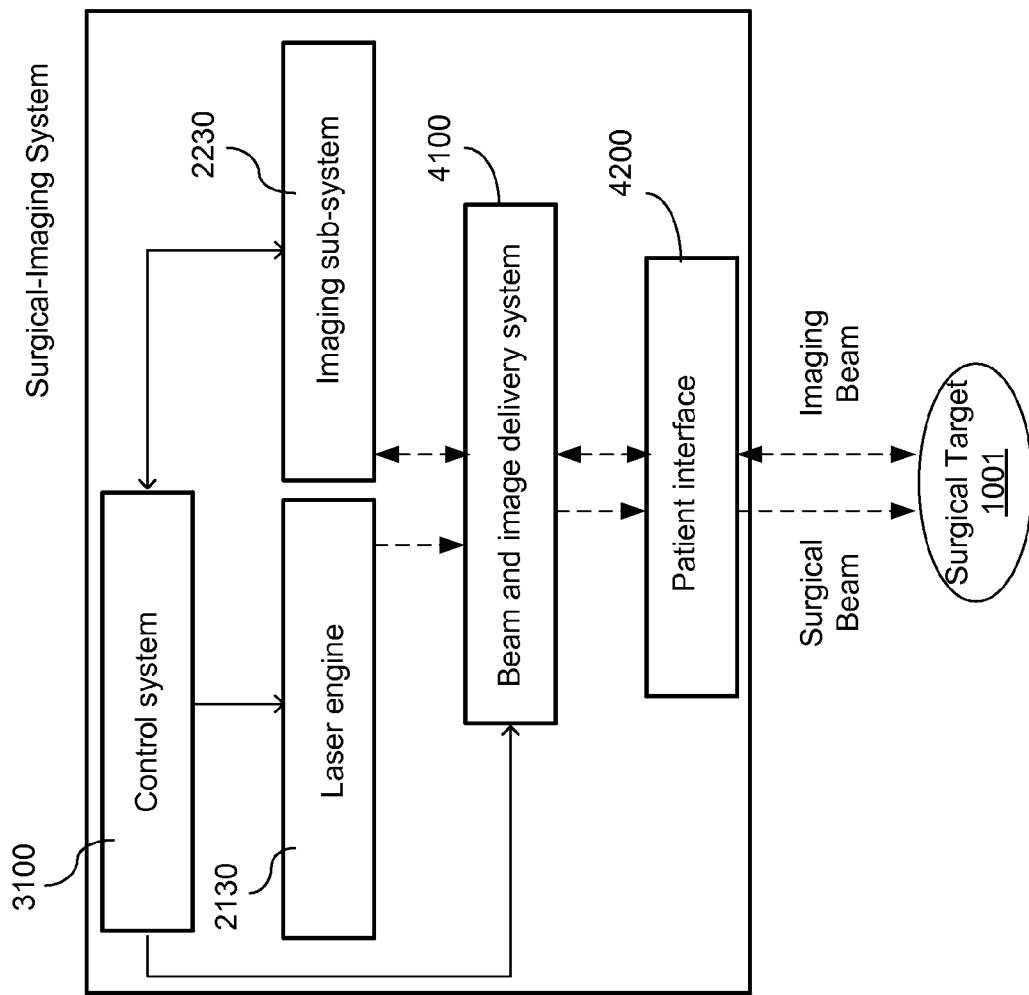
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FIG. 10



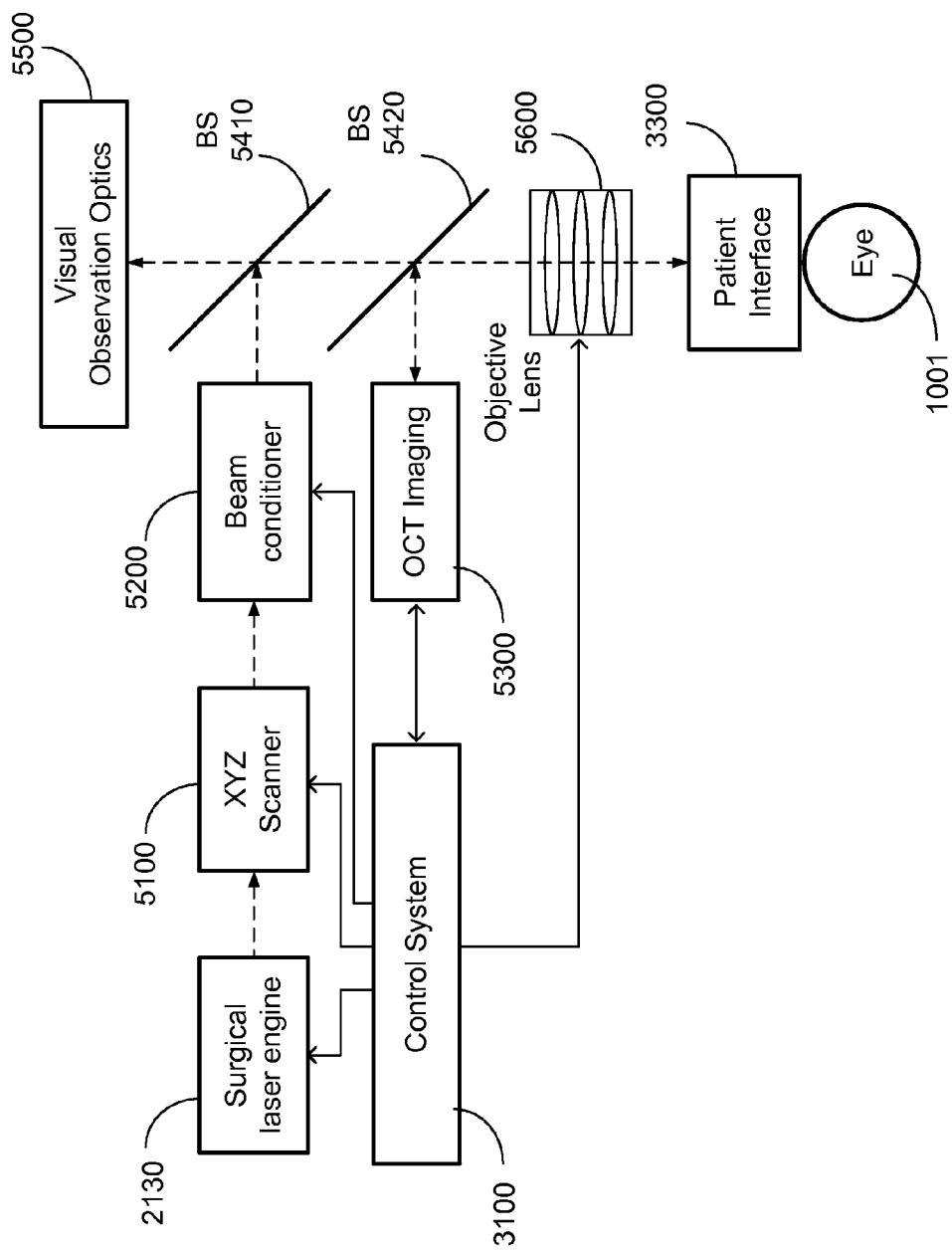
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FIG. 11



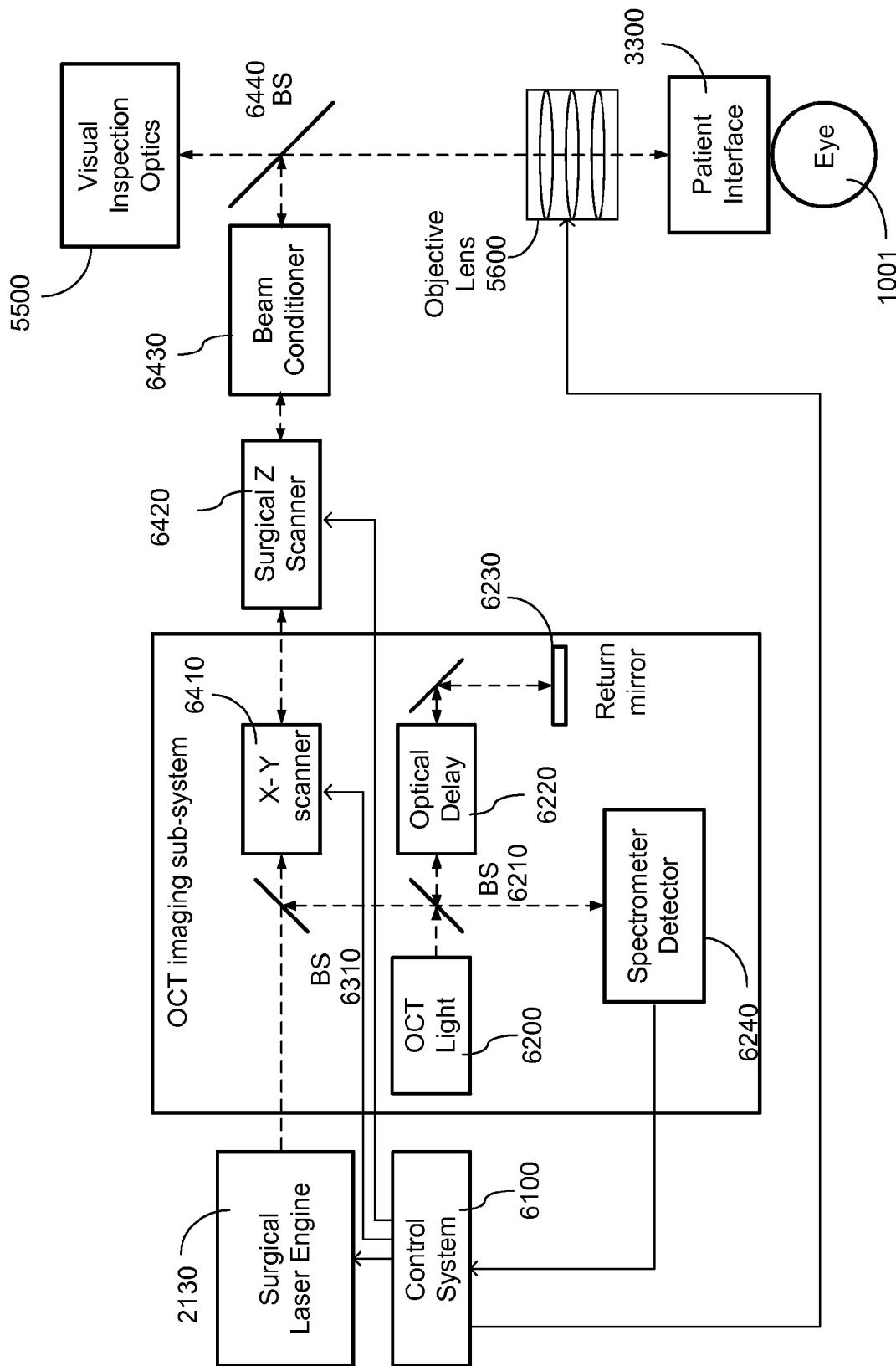
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FIG. 12



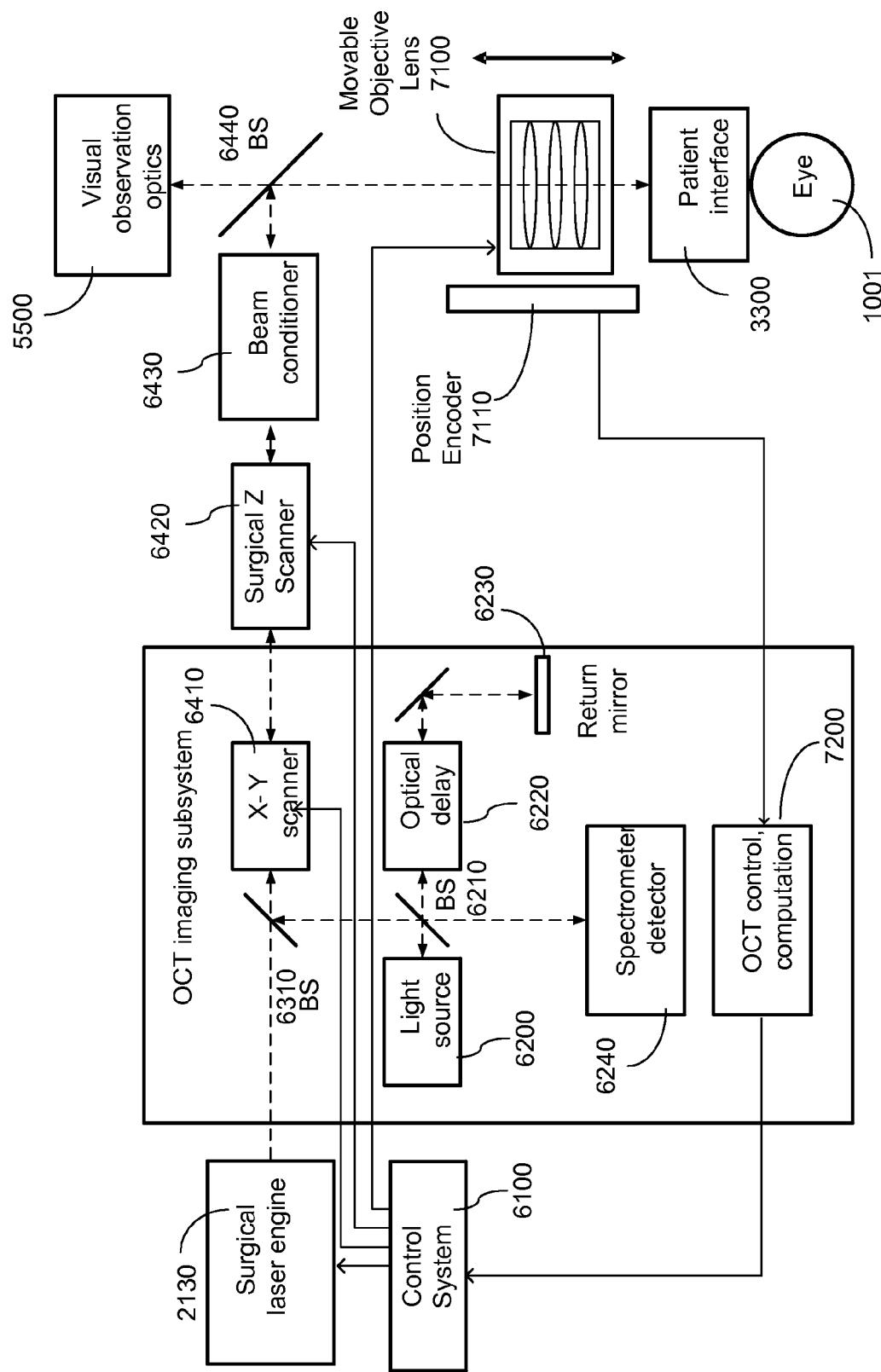
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FIG. 13



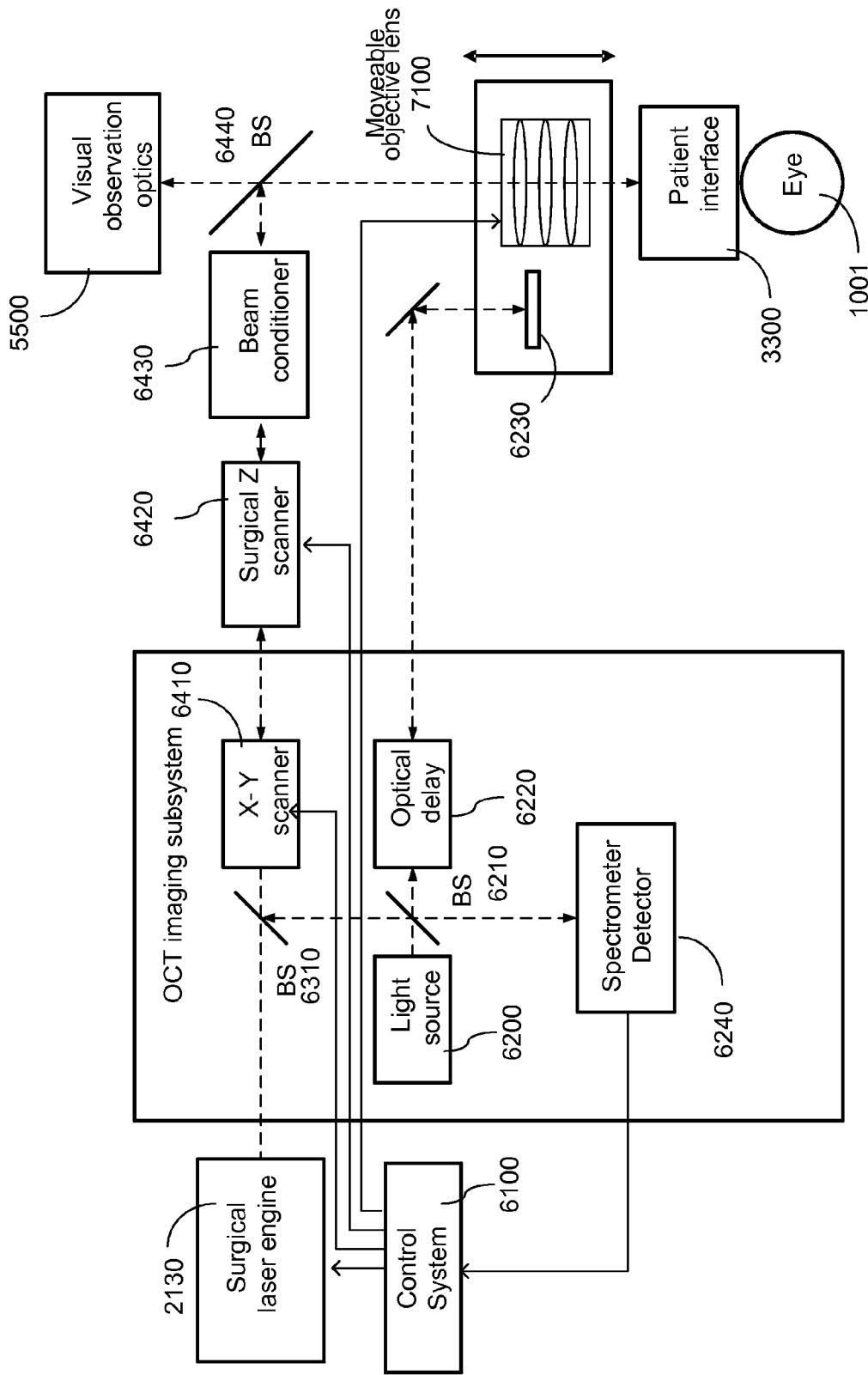
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FIG. 14



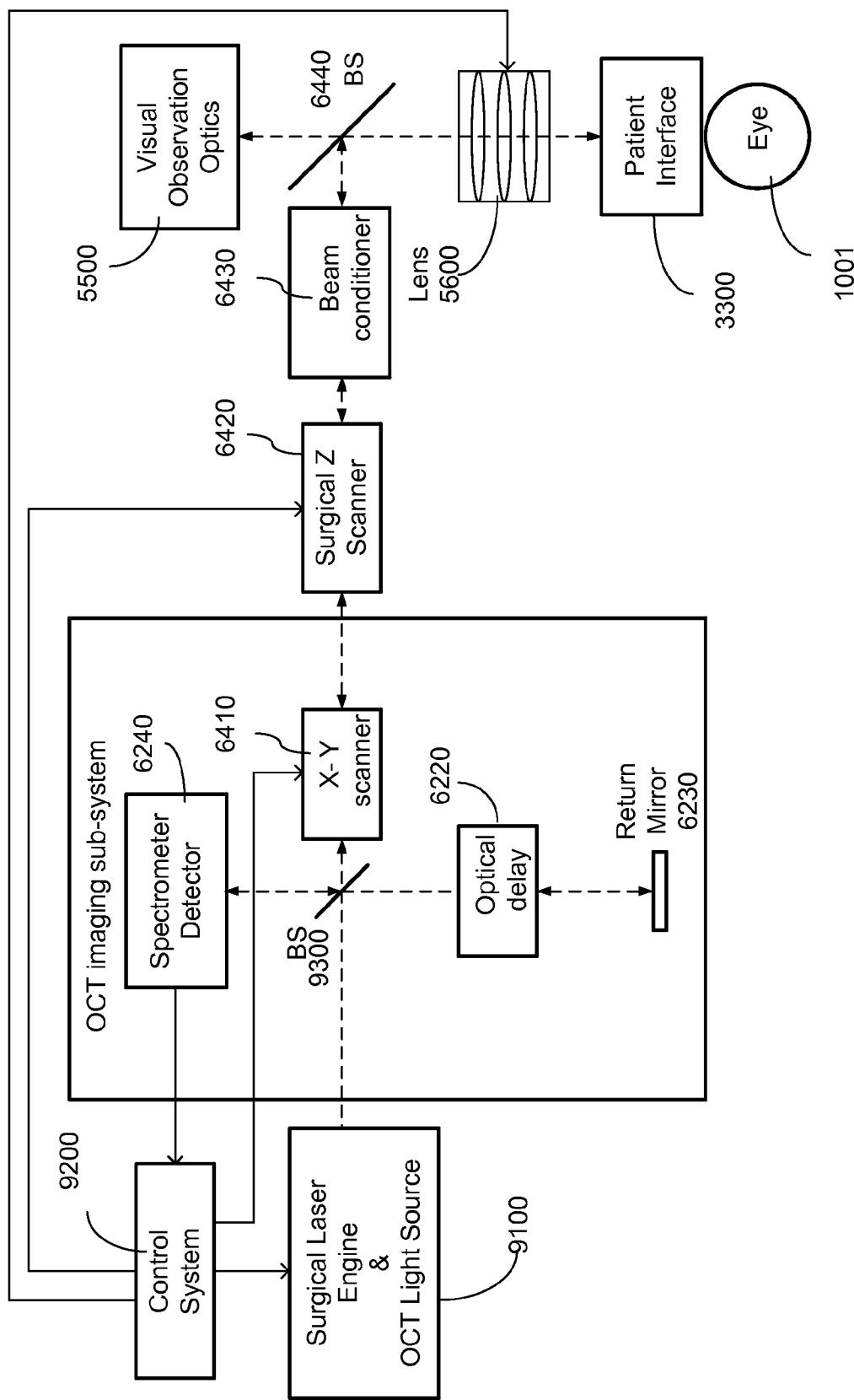
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FIG. 15



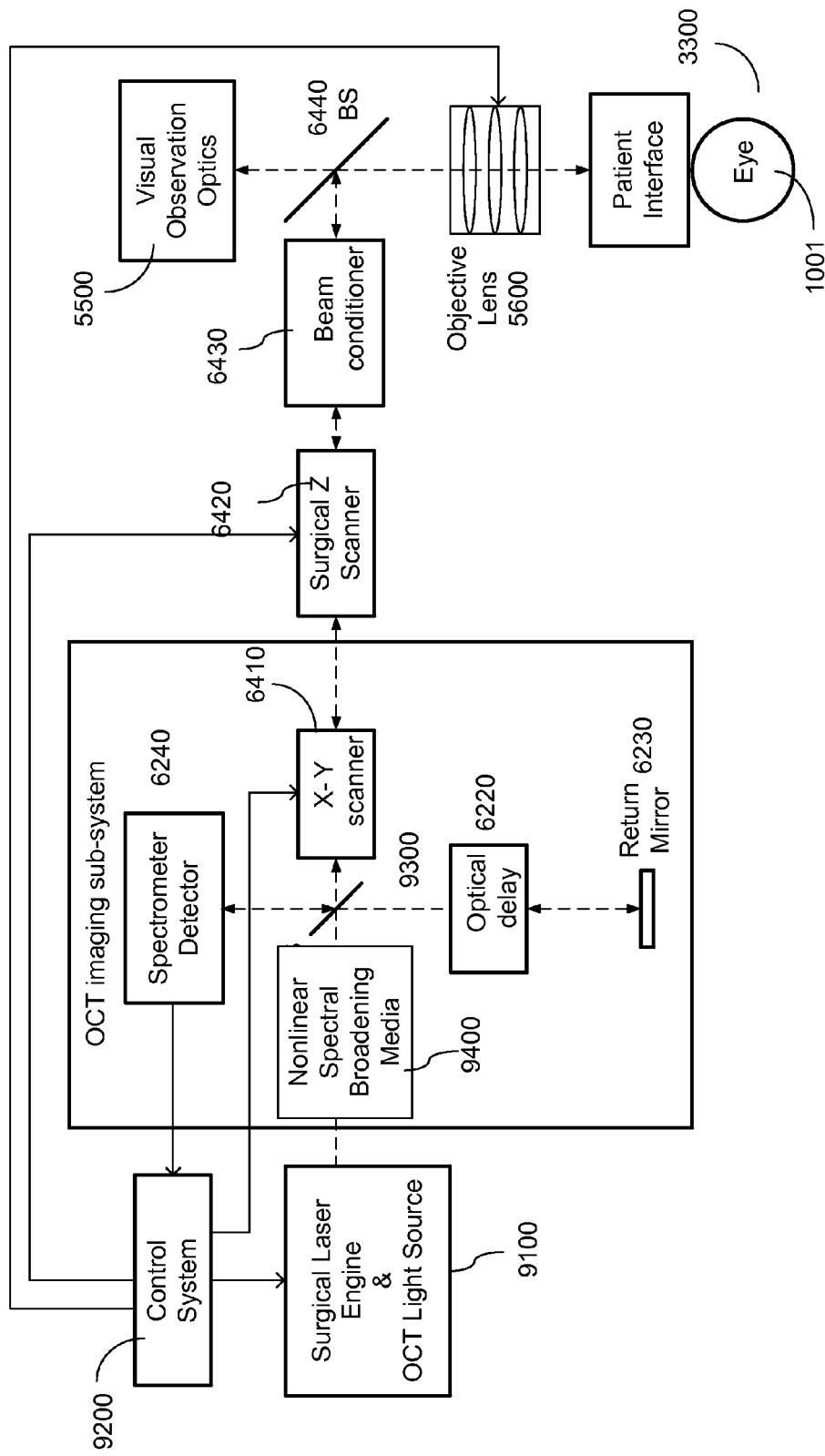
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FIG. 16



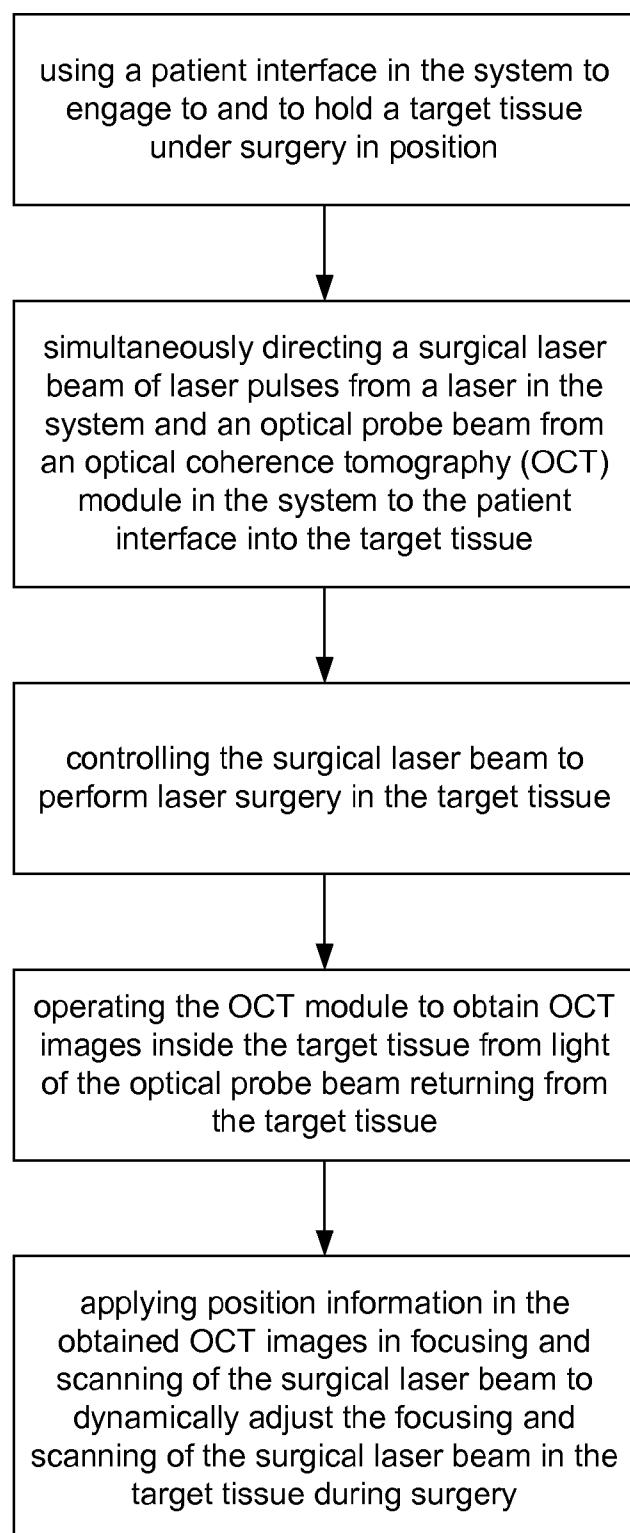
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FIG. 17



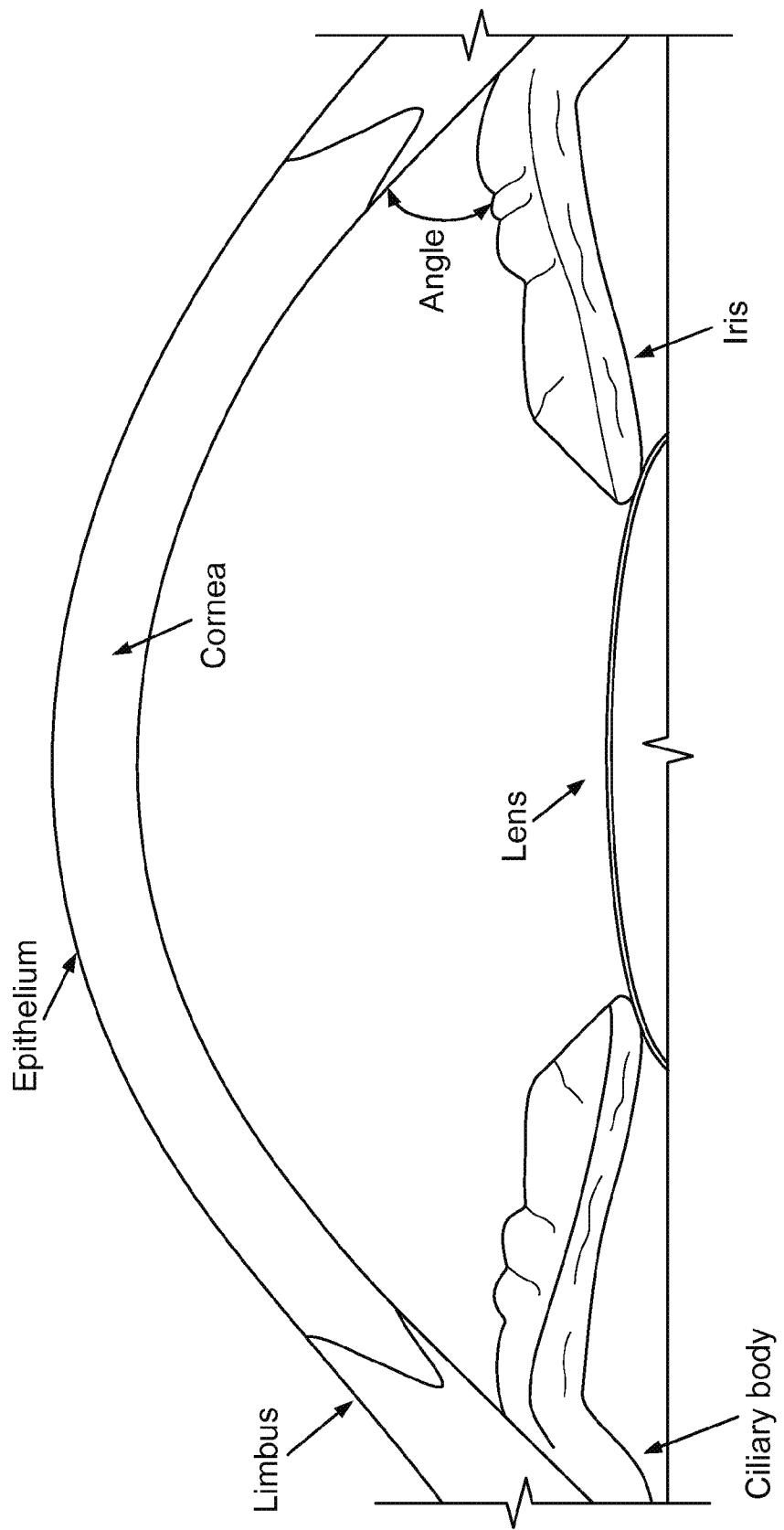
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FIG. 18



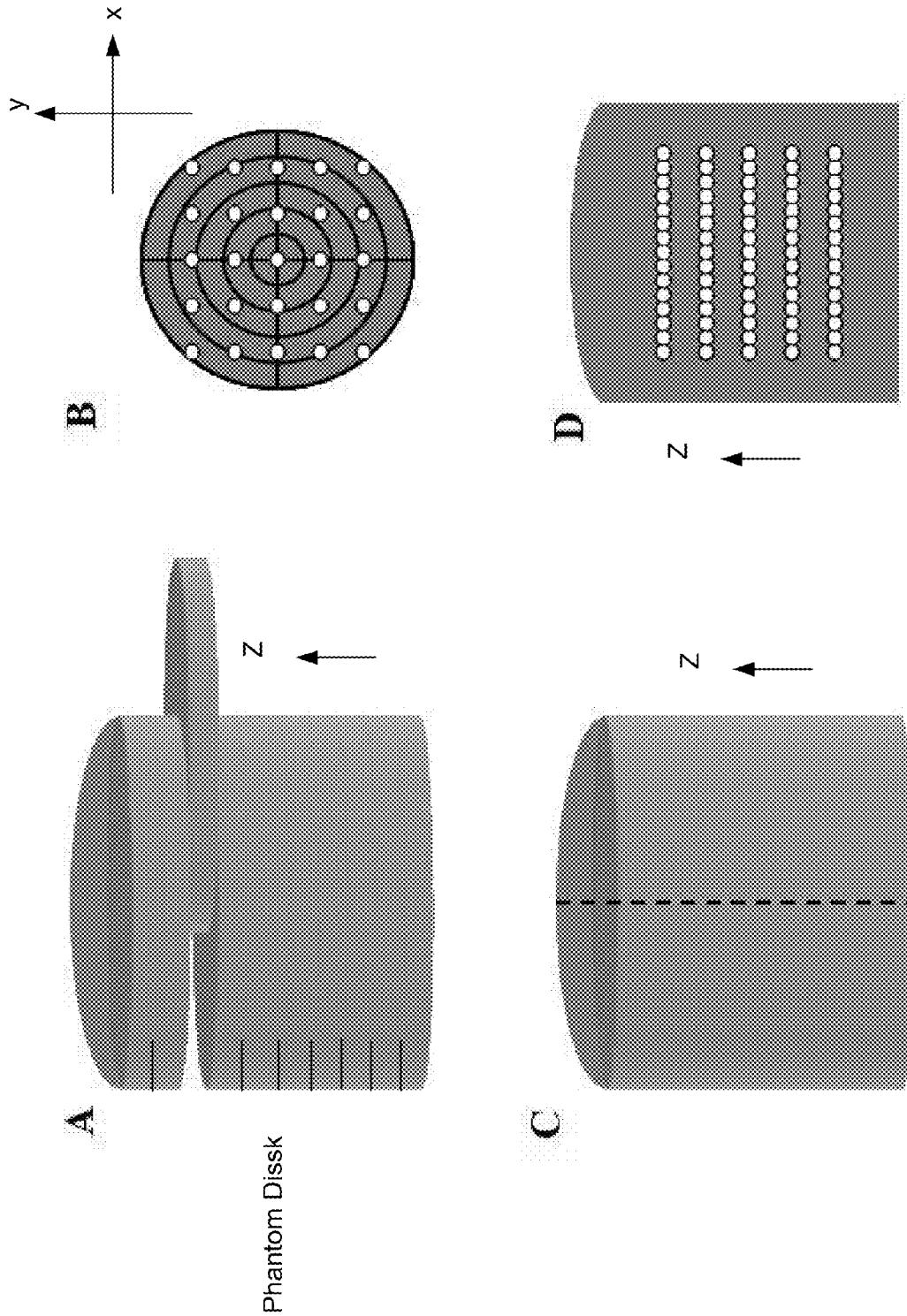
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FIG. 19



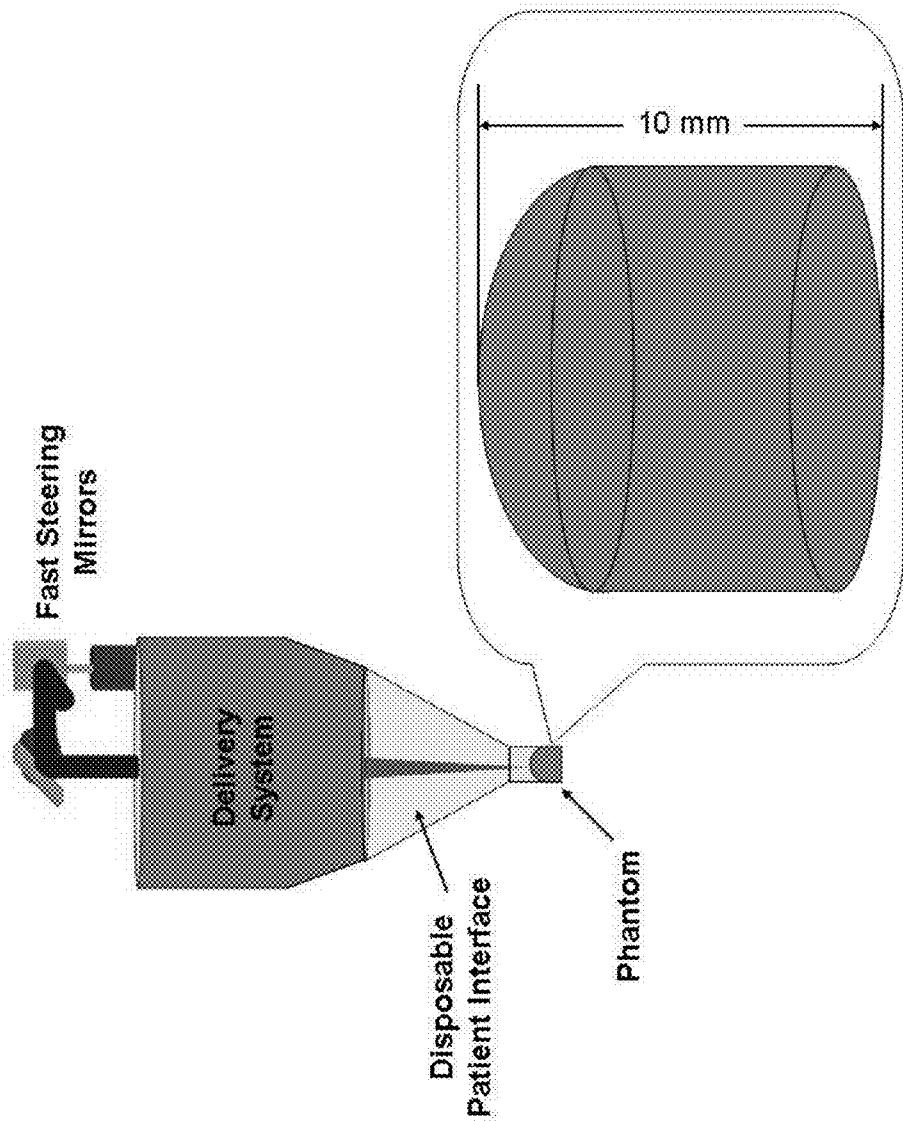
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FIG. 20



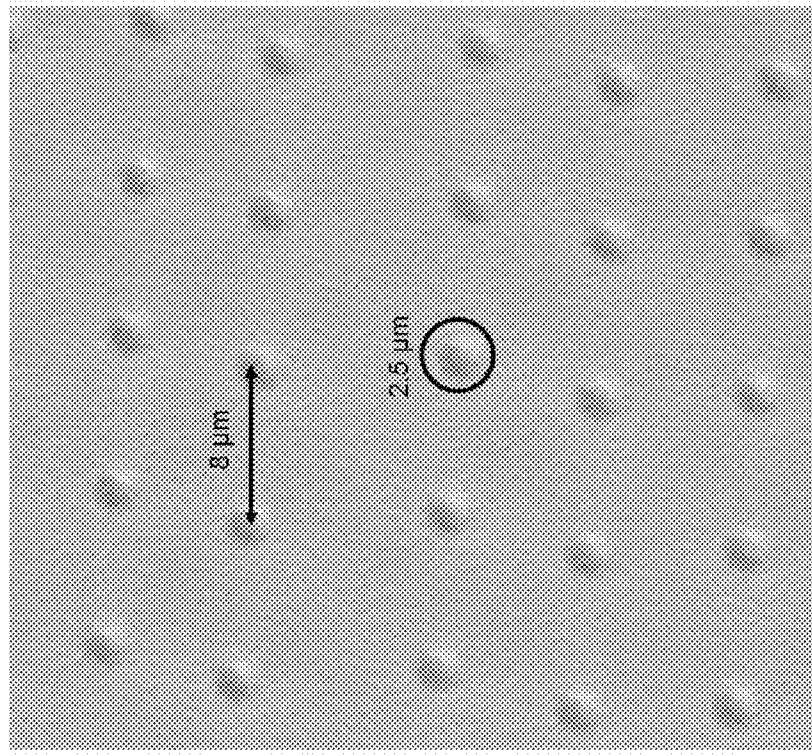
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FIG. 21



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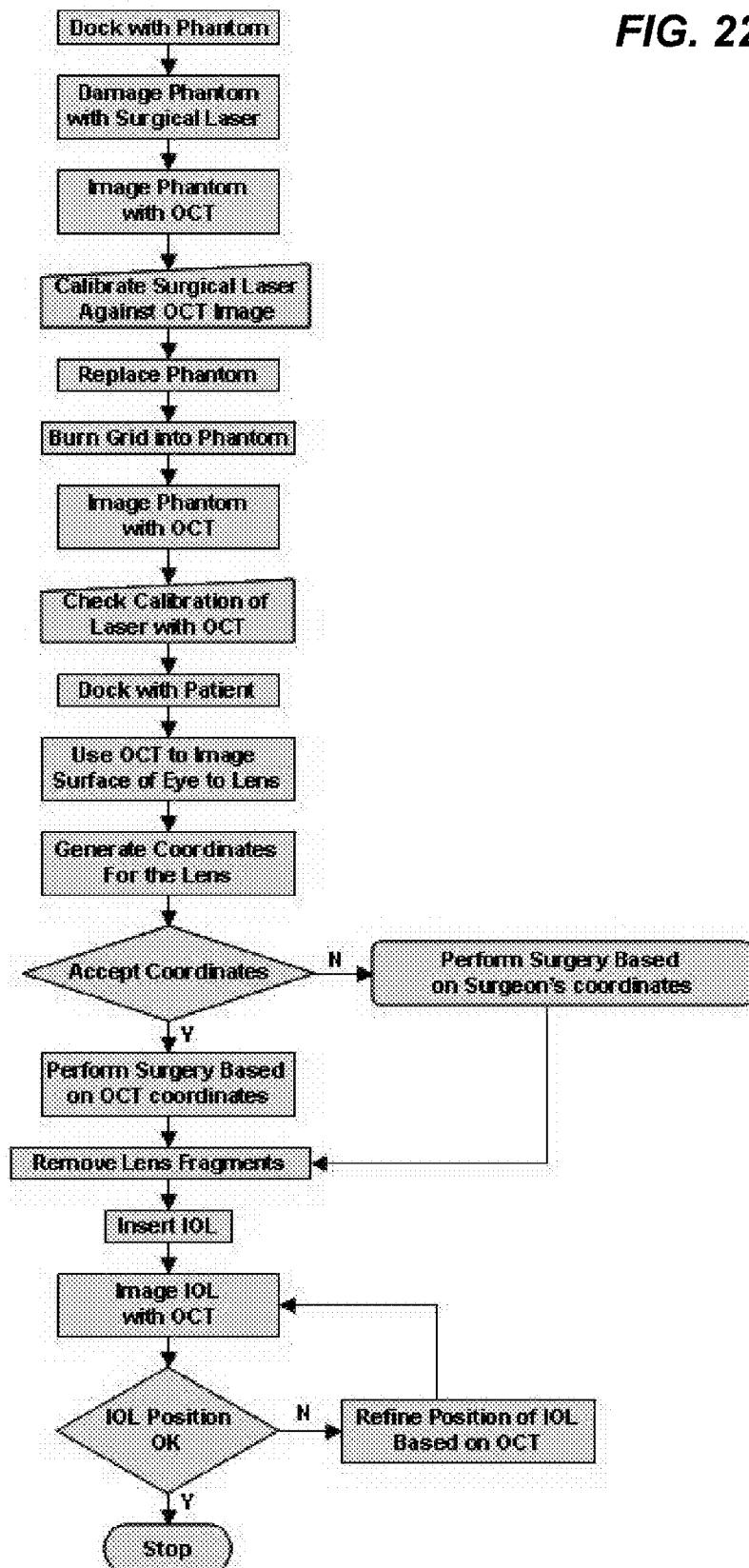


FIG. 22

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FIG. 23A

Diagnostic Mode

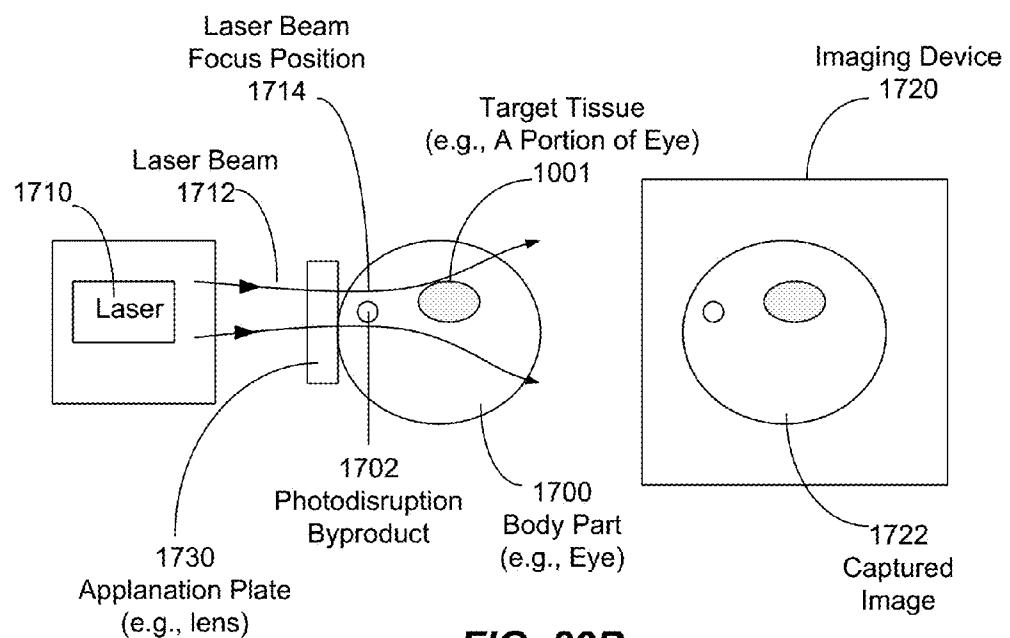
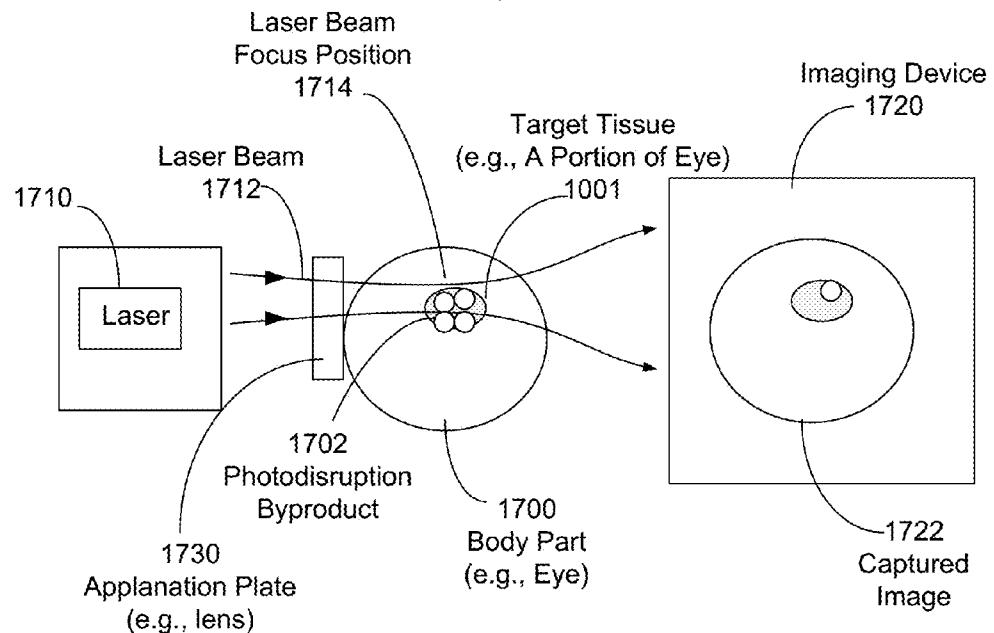


FIG. 23B

Surgical Mode



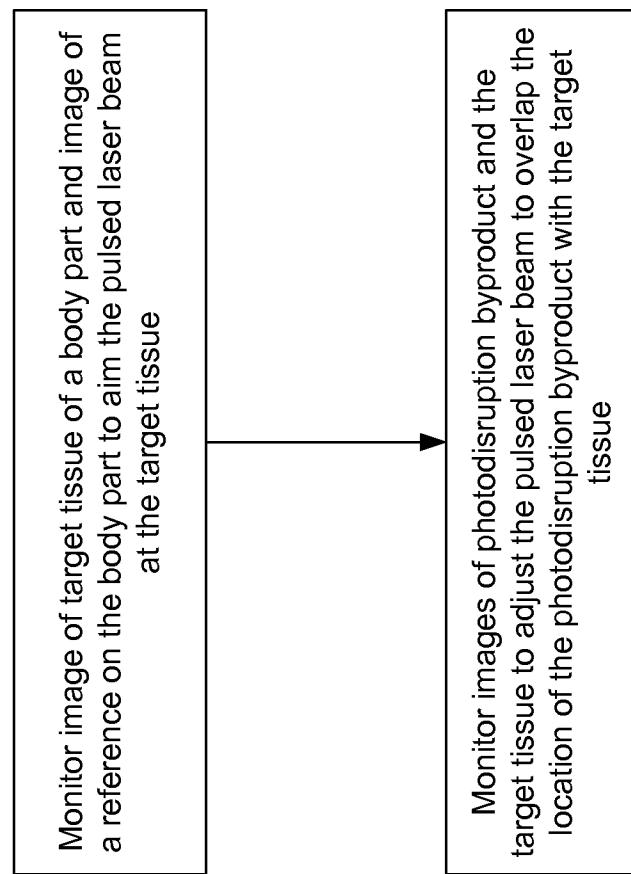
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FIG. 24



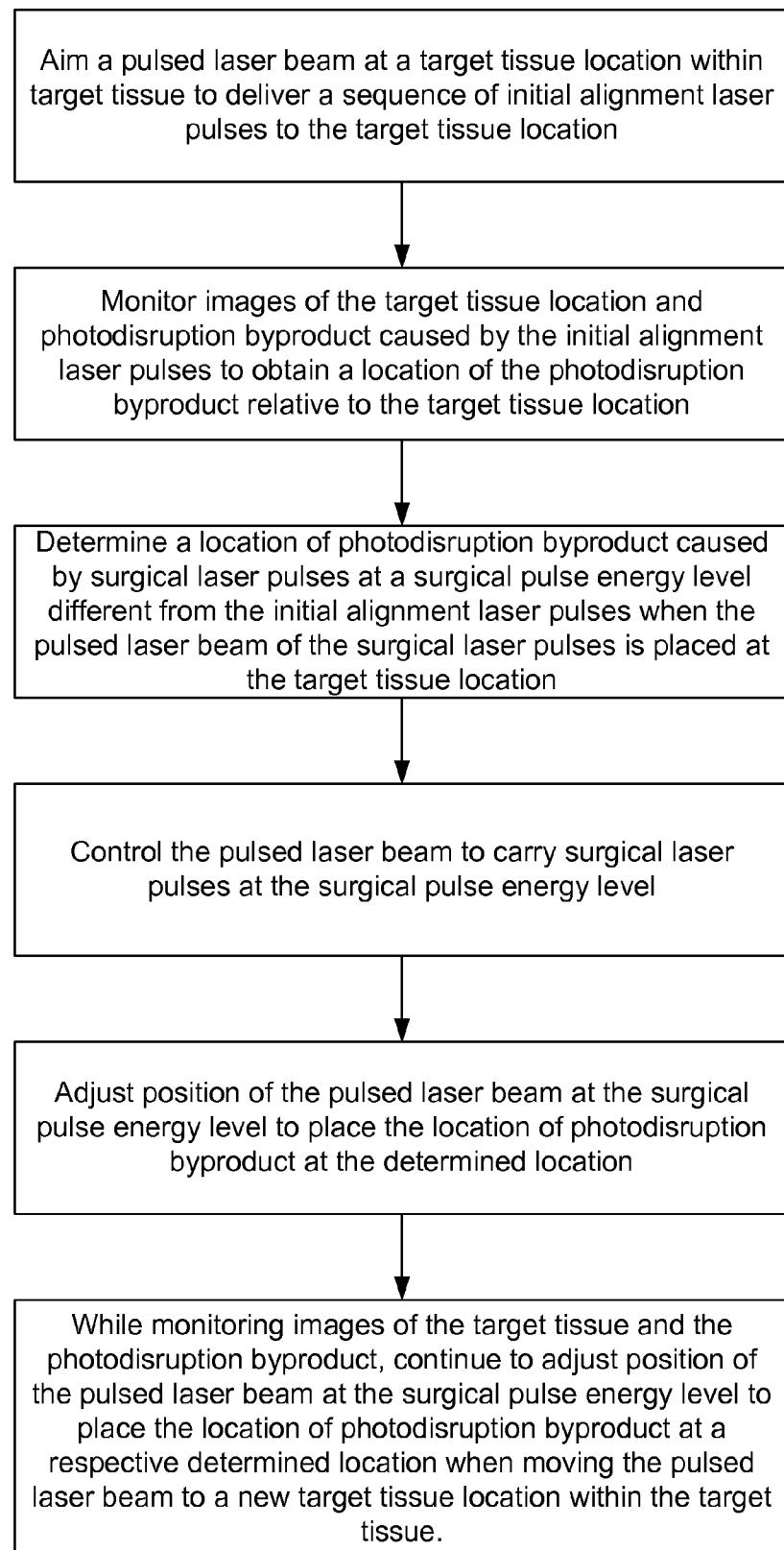
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FIG. 25



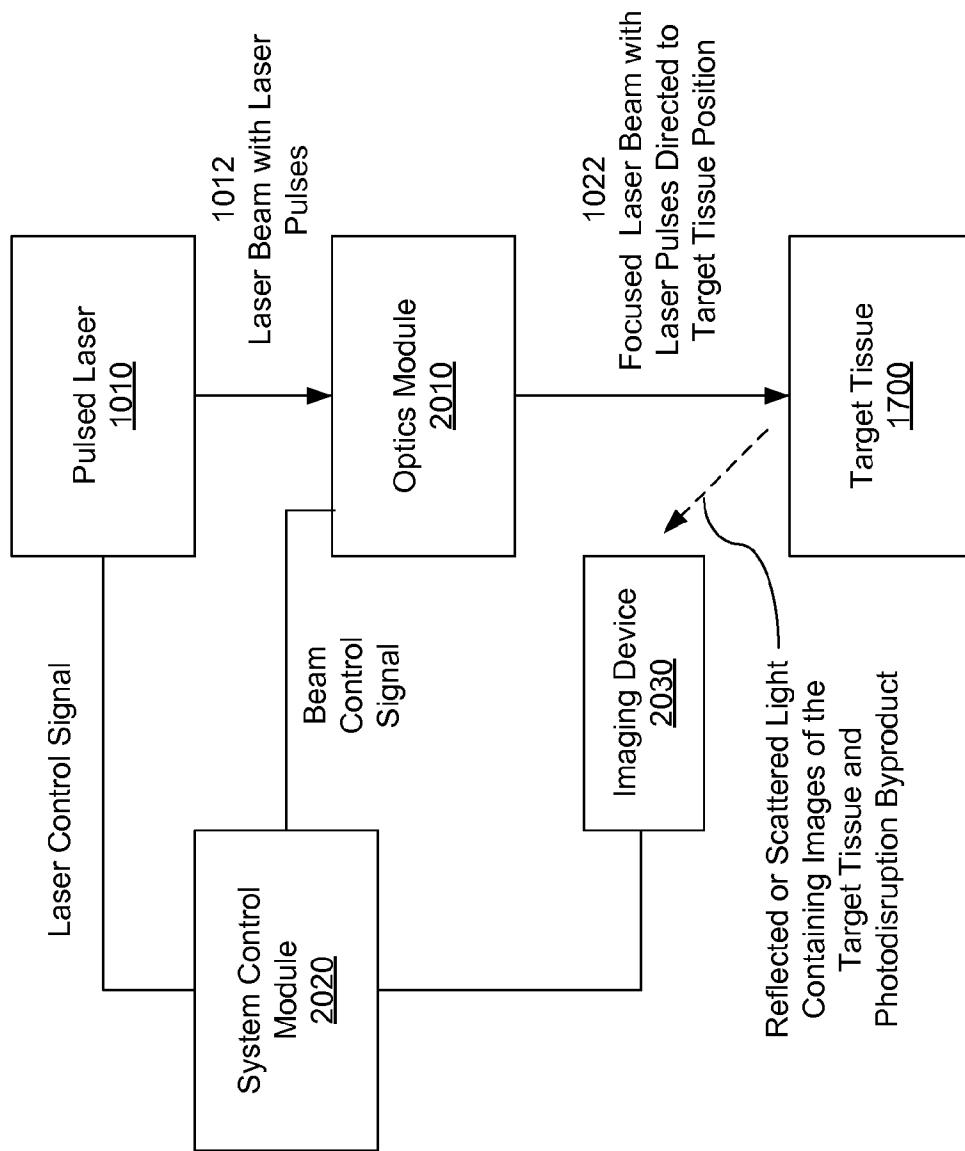
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FIG. 26



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**PHOTODISRUPTIVE LASER TREATMENT
OF THE CRYSTALLINE LENS**

**CROSS-REFERENCE TO RELATED
APPLICATION**

This application is a continuation-in-part of U.S. patent application Ser. No. 12/205,842, filed Sep. 5, 2008, now abandoned entitled "Photodisruptive Laser Treatment of the Crystalline Lens" and filed by Ronald M. Kurtz, which claims priority to and benefit of U.S. provisional application Ser. No. 60/970,454, filed Sep. 6, 2007, entitled "Photodisruptive Laser Treatment of the Crystalline Lens" and filed by Ronald M. Kurtz. The entire disclosures of the above two applications are incorporated by reference as part of the disclosure of this application.

BACKGROUND

This application relates to laser eye surgery of the crystalline lens using photodisruption caused by laser pulses.

Surgical procedures for removal of the crystalline lens utilize various techniques to break up the lens into small fragments that can be removed from the eye through incisions. Some of these procedures use manual instruments, ultrasound, heated fluids or lasers. One of the significant drawbacks of these methods is the need to actually enter the eye with probes in order to accomplish the fragmentation. This typically requires making large incisions on the lens and limits the precision associated with such lens fragmentation techniques.

Photodisruptive laser technology can deliver laser pulses into the lens to optically fragment the lens without insertion of a probe and thus is potentially a less intrusive procedure, offering higher precision and control.

Laser-induced photodisruption has been already used in the past in laser ophthalmic surgery. In the target region the laser ionizes a portion of the molecules, eventually releasing gases, which, in an expansion phase, disrupt and break up the lens material in the target region. In some cases Nd:YAG lasers have been employed as the laser sources.

Lens fragmentation via laser-induced photodisruption has also been proposed. For example, L'Esperance in U.S. Pat. No. 4,538,608 disclosed an apparatus for lens tissue destruction which included a viewing system, a laser and a means for optical delivery and scanning of the focal spot of laser pulses. The laser pulses were focused on the anterior plane of the lens and were moved progressively deeper into the lens to achieve cataract material destruction. In U.S. Pat. No. 5,246,435, Bille proposed an alternative approach that focused the laser pulses first in a posterior region of the lens and then move the focus in a posterior to anterior direction. In this method the laser reached the target regions with less distortion from the already treated regions, thus affording greater control. However, various technical problems remain unresolved.

SUMMARY

Apparatus and methods of treating a hard lens region of an eye with a laser are provided. Implementations of a method of treating a crystalline lens of an eye with a laser include selecting a surgical region of the lens, applying laser pulses to form at least one incision within the selected surgical region, wherein an orientation of the incision is one of an orientation intersecting fibers of the lens and an

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orientation non-transverse to an axis of the eye, and the incision modifies a property of the lens.

In some implementations the non-transverse orientation of the incision is an orientation substantially parallel to the axis of the eye or an orientation making a less than 90 degree angle with the axis of the eye.

In some implementations a spatial extent of the incision along the axis of the eye is longer than the spatial extent transverse to the axis of the eye.

10 In some implementations the spatial extent along the axis of the eye is in the range of 0.5 mm-12 mm and the spatial extent transverse to the axis of the eye is in the range of 1-500 microns. In some implementations the axis of the eye is one of a visual axis, an optic axis, a line of sight and a pupillary axis.

15 In some implementations the incision cuts the fibers into parts approximately at the intersection of the incision and the fibers and the modified property of the lens is a weakening of a biomechanical property of the lens.

20 In some implementations the incision cuts the fibers at or near sutures of the fibers.

25 In some implementations the incision avoids cutting sutures in the lens.

30 In some implementations the applying laser pulses includes applying the laser pulses to generate gas bubbles which form the incision, wherein an orientation of the incision is aligned with a preferential direction of expansion of the generated gas bubbles.

35 In some implementations the applying the laser pulses includes moving the focal point of the applied laser beam along a posterior to anterior direction within the lens.

40 In some implementations the incision has one of an extent at least equal to an extent of a nucleus of the lens, an X-Y diameter in excess of 2 mm and a Z extent in excess of 0.5 mm, and an X-Y diameter in excess of 4 mm and a Z extent in excess of 1 mm, wherein the X-Y diameter is a measure of the spatial extent of the entire incision in the direction transverse to the axis.

45 In some implementations the method includes forming no more than one incision and the laser pulses are applied in a continuous manner to form the incision without repositioning the laser or interrupting the application of the laser.

50 In some implementations the incision has a form aligned with the axis of the eye, the form being of at least one of a cylinder, a set of concentric cylinders, a set of cylinders connected by one or more connecting line, a curved surface, a cone, a spiral, a layered spiral with smooth lines connecting layers of the spiral and a tilted cylinder.

55 In some implementations the incision has a form aligned with the axis of the eye, the form being at least one of a plane, two or more crossing planes, a combination of planes and connecting arcs, and a combination of planes and cylinders.

60 In some implementations the applying the laser pulses includes forming incisions in a layer-by-layer manner.

65 In some implementations the forming the incisions in a layer-by-layer manner includes applying laser pulses to target locations within a posterior layer of the lens, the target locations belonging to two incisions or two segments of the same incision and applying laser pulses to target locations within a layer anterior to the posterior layer, the target locations belonging to the same two incisions or to the same two segments of the same incision.

In some implementations the applying the laser pulses includes applying the laser pulses to form a first ring with a first radius in a posterior layer of the lens, applying the laser pulses to form a connector line between the first and a

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second ring in the posterior layer, applying the laser pulses to form the second ring with a second radius in the posterior layer, and repeating multiple times the formation of the first ring, the second ring and the connector line in layers sequentially anterior to the posterior layer, wherein the first rings in the sequential layers form a first cylinder, the second rings form a second cylinder, the cylinders being connected by the connector lines.

In some implementations the connector lines in sequential layers are one of aligned to form connector planes and not-aligned from layer to layer.

Some implementations include forming a posterior spiral in a posterior layer, forming a smooth connector line starting near an end of the spiral in the posterior layer, the connector line smoothly bending and rising to a central region of a layer anterior to the posterior layer and forming an anterior spiral starting at the end of the smooth connector line in the central region of the anterior layer.

In some implementations the posterior spiral and the anterior spiral are essentially aligned to form a spiral with an extent in the Z direction.

In some implementations the applying the laser pulses includes selecting laser-parameters sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye.

In some implementations the applying the laser pulses includes applying the laser pulses with laser-parameters insufficient to fragment the lens to a degree suitable for removal, if the incision were transverse to the axis of the eye.

In some implementations the laser-parameters include a laser pulse energy in the range of 0.5 microJ to 50 microJ, a duration of a laser pulse in the range of 0.005 picoseconds to 25 picoseconds, a repetition rate of applying laser pulses in the range of 1 kHz to 10 MHz, and a separation distance of target regions of laser pulses in the range of 1 micron to 100 microns.

In some implementations the applying the laser pulses includes applying the laser pulses with varying energy as the incision is formed.

In some implementations the energy is varied during at least one of a Z directional scanning and an X-Y directional scanning.

In some implementations the energy is varied in relation to a measurement of an optical property of an eye tissue.

Some implementations include forming the incision on a layer-by-layer basis, wherein one or more layers are at least partially formed along a curved focal plane of a laser delivery system.

In some implementations a Z directional scanner is adjusted at a slower rate than an X-Y directional scanner when forming a layer of one or more incisions.

Some implementations further include forming a protection layer in a posterior portion of the lens, positioned to block a large portion of the laser pulses applied to form the incision.

In some implementations the incision fragments at least a portion of the lens, the method further including removing the fragmented portion of the lens.

In some implementations the applying the laser pulses includes applying laser pulses with laser parameters which do not cause lasting damage to a retina of the eye, wherein the laser pulses fragment the lens to a degree suitable for removal and the time of the fragmentation is less than a minute.

Some implementations include applying laser pulses to form an incision in a lens of an eye, wherein the laser pulses

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are applied by a laser system which is configured to scan the laser pulses in the entire nucleus of the lens without interrupting the application of the laser pulses.

In some implementations the incision intersects fibers of the lens.

In some implementations at least segments of the incision are essentially non-transverse to an axis of the eye.

In some implementations the incision is one of a cylinder, a set of concentric cylinders, a set of concentric cylinders connected by connecting lines, a cone, crossing planes, crossing planes connected by arcs, a spiral, and a layered spiral with a smooth line connecting layers of the spiral.

Some implementations include a laser system for fragmenting a crystalline lens of an eye, including a pulsed laser configured to generate a laser beam of laser pulses and an optical delivery system, wherein the optical delivery system is configured to apply the laser beam to create an incision in the lens of the eye with a spatial extent along an axis of the eye longer than 2 mm and a spatial diameter transverse to the axis of the eye larger than 4 mm without interrupting the application of the laser.

In some implementations the optical delivery system is configured to move a focal point of the laser in a posterior to anterior direction of the lens.

In some implementations the optical delivery system is configured to control the laser to generate a laser beam with laser-parameters sufficient to create photodisruption in a selected lens region and insufficient to cause damage to a retina of the eye.

In some implementations the optical delivery system is configured to control the pulsed laser to generate laser pulses with laser-parameters an energy in the range of approximately 0.5 microJ to 50 microJ, a separation of adjacent target areas in the range of approximately 1 micron to 100 microns, a duration in the range of approximately 0.005 picoseconds to 25 picoseconds and a repetition rate in the range of 1 kHz to 10 MHz.

40 BRIEF DESCRIPTION OF FIGURES

FIG. 1 illustrates an overview of an eye.

FIG. 2 illustrates a structure of a lens of an eye, including a reduced transparency region.

FIGS. 3A-B illustrate the generation and spreading of bubbles in a photodisruptive treatment of a lens.

FIG. 4 illustrates the steps of a photodisruptive treatment of a lens.

FIGS. 5A-C illustrate the steps of a photodisruptive procedure.

FIGS. 5D-K illustrate various configurations of incisions.

FIG. 6 illustrates a step of determining a boundary of the hard lens region.

FIG. 7 shows an example of an imaging-guided laser surgical system in which an imaging module is provided to provide imaging of a target to the laser control.

FIGS. 8-16 show examples of imaging-guided laser surgical systems with varying degrees of integration of a laser surgical system and an imaging system.

FIG. 17 shows an example of a method for performing laser surgery by suing an imaging-guided laser surgical system.

FIG. 18 shows an example of an image of an eye from an optical coherence tomography (OCT) imaging module.

FIGS. 19A, 19B, 19C and 19D show two examples of calibration samples for calibrating an imaging-guided laser surgical system.

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FIG. 20 shows an example of attaching a calibration sample material to a patent interface in an imaging-guided laser surgical system for calibrating the system.

FIG. 21 shows an example of reference marks created by a surgical laser beam on a glass surface.

FIG. 22 shows an example of the calibration process and the post-calibration surgical operation for an imaging-guided laser surgical system.

FIGS. 23A and 23B show two operation modes of an exemplary imaging-guided laser surgical system that captures images of laser-induced photodisruption byproduct and the target issue to guide laser alignment.

FIGS. 24 and 25 show examples of laser alignment operations in imaging-guided laser surgical systems.

FIG. 26 shows an exemplary laser surgical system based on the laser alignment using the image of the photodisruption byproduct.

DETAILED DESCRIPTION

FIG. 1 illustrates the overall structure of the eye. The incident light propagates through the optical path which includes the cornea, the anterior chamber, the pupil, the posterior chamber, the lens and the vitreous humor. These optical elements guide the light on the retina.

FIG. 2 illustrates a lens 100 in more detail. The lens 100 is sometimes referred to as crystalline lens because of the α , β , and γ crystalline proteins which make up about 90% of the lens. The crystalline lens has multiple optical functions in the eye, including its dynamic focusing capability. The lens is a unique tissue of the human body in that it continues to grow in size during gestation, after birth and throughout life. The lens grows by developing new lens fiber cells starting from the germinal center located on the equatorial periphery of the lens. The lens fibers are long, thin, transparent cells, with diameters typically between 4-7 microns and lengths of up to 12 mm. The oldest lens fibers are located centrally within the lens, forming the nucleus. The nucleus 101 can be further subdivided into embryonic, fetal and adult nuclear zones. The new growth around the nucleus 101, referred to as cortex 103, develops in concentric ellipsoid layers, regions, or zones. Because the nucleus 101 and the cortex 103 are formed at different stages of the human development, their optical properties are distinct. While the lens increases in diameter over time, it may also undergo compaction so that the properties of the nucleus 101 and the surrounding cortex 103 may become even more different (Freel et al, BMC Ophthalmology 2003, vol. 3, p. 1).

As a result of this complex growth process, a typical lens 100 includes a harder nucleus 101 with an axial extent of about 2 mm, surrounded by a softer cortex 103 of axial width of 1-2 mm, contained by a much thinner capsule membrane 105, of typical width of about 20 microns. These values may change from person to person to a considerable degree.

Lens fiber cells undergo progressive loss of cytoplasmic elements with the passage of time. Since no blood veins or lymphatics reach the lens to supply its inner zone, with advancing age the optical clarity, flexibility and other functional properties of the lens sometimes deteriorate.

FIG. 2 illustrates, that in some circumstances, including long-term ultraviolet exposure, exposure to radiation in general, denaturation of lens proteins, secondary effects of diseases such as diabetes, hypertension and advanced age, a region of the nucleus 101 can become a reduced transparency region 107. The reduced transparency region 107 is usually a centrally located region of the lens (Sweeney et al Exp. Eye res, 1998, vol. 67, p. 587-95). This progressive loss

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of transparency often correlates with the development of the most common type of cataract in the same region, as well as with an increase of lens stiffness. This process may occur with advancing age in a gradual fashion from the peripheral to the central portion of the lens (Heys et al Molecular Vision 2004, vol. 10, p. 956-63). One result of such changes is the development of presbyopia and cataract that increase in severity and incidence with age.

The reduced transparency region 107 can be removed via cataract surgery. A common procedure is to make an incision into the capsule of the cloudy lens (capsulotomy) and surgically remove the interior, i.e. the cortex and the nucleus, while leaving the lens capsule intact. This is the so-called extra capsular surgery. While the cortex exhibits viscous fluid dynamics and thus can be removed by aspiration or even simple suction, the nucleus is too hard for this approach and is typically removed as a whole. Finally, a plastic "intraocular" lens is often inserted as a replacement into the capsule. This procedure requires making a quite large incision, sometimes up to 12 mm. Creating incisions of this size can lead to a variety of problems, as described below.

In some methods, the use of ultrasound waves was introduced into cataract surgery. In this "phacoemulsification" procedure one or more smaller incisions are made on the capsule 105 and an ultrasound agitator, or "phaco-probe" is introduced into the lens. Operating the agitator or phaco-probe emulsifies the nucleus, which allows the removal of the emulsified nucleus via aspiration through an incision smaller than the previous technique.

However, even the phacoemulsification technique requires making an incision on the capsule 105, sometimes up to 7 mm. The procedure can leave extensive unintended modifications in its wake: the treated eye can exhibit extensive stigmatism and a residual or secondary refractive or other error. This latter often necessitates a follow-up refractive or other surgery or device.

In recent developments, considerable effort was focused on developing a large variety of the intraocular lenses for insertion into the capsule 105. The examples include even bifocal lenses. However, there wasn't much progress in the area of improving the removal process involving the lens 100 or the nucleus 101.

Implementations of the present application include photodisruptive methods instead of phacoemulsification to break up a hard lens region 109. Since no phaco probe is inserted into the lens 100, a much smaller incision is necessitated only for the subsequent aspiration of the broken-up nucleus. This reduces the unintended secondary effects, and can reduce the percentage of patients who need secondary refractive or other surgery.

The hard lens region 109 often coincides with the nucleus 101. However, numerous variations may occur. E.g. the outermost soft layers of the nucleus may be removable by aspiration or even suction and thus may not require photodisruptive methods. In other cases, only the cataract-impacted portion of the eye may be disrupted for subsequent removal. In yet other cases it may be desired that only a portion of the nucleus 101 is disrupted, when the nucleus is only sculpted and not removed. To express the broader scope of the contemplated variations, all these regions will be jointly referred to as the hard lens region 109. The nucleus 101 is only one embodiment of the hard lens region 109.

In some cases this hard lens region 109 may occupy an ellipsoid-like region of approximately 6-8 mm in equatorial diameter and approximately 2-3.5 mm in axial diameter, or

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extent. The size of this hard lens region 109 may be different for different patients, for different diseases and for different procedures.

In a laser-induced lens fragmentation process, laser pulses ionize a portion of the molecules in the target region. This may lead to an avalanche of secondary ionization processes above a “plasma threshold”. In many surgical procedures a large amount of energy is transferred to the target region in short bursts. These concentrated energy pulses may gasify the ionized region, leading to the formation of cavitation bubbles. These bubbles may form with a diameter of a few microns and expand with supersonic speeds to 50-100 microns. As the expansion of the bubbles decelerates to subsonic speeds, they may induce shockwaves in the surrounding tissue, causing secondary disruption.

Both the bubbles themselves and the induced shockwaves carry out a goal of the procedure: the disruption, fragmentation or emulsification of the targeted hard lens region 109 without having made an incision on the capsule 105. The disrupted hard lens region 109 can then be removed through a much smaller incision, possibly without inserting a surgical device into the lens itself.

However, the photodisruption decreases the transparency of the affected region. Remarkably, the lens of the eye has the highest density of proteins of all tissues, yet it is transparent. For this same reason, however, the transparency of the lens is particularly sensitive to structural changes, including the presence of bubbles and damage by shockwaves.

If the application of the laser pulses starts with focusing them in the frontal or anterior region of the lens and then the focus is moved deeper towards the posterior region, the cavitation bubbles and the accompanying reduced transparency tissue can be in the optical path of the subsequent laser pulses, blocking, attenuating or scattering them. This may diminish the precision and control of the application of the subsequent laser pulses, as well as reduce the energy pulse actually delivered to the deeper posterior regions of the lens. Therefore, the efficiency of laser-based eye surgical procedures can be enhanced by methods in which the bubbles generated by the early laser pulses do not block the optical path of the subsequent laser pulses.

Various approaches, including the technique of U.S. Pat. No. 5,246,435, do not provide an effective way of addressing the above adverse interference by bubbles produced by preceding laser pulses. Thus, prior methods often require the use of additional lens fragmentation techniques in addition to the photodisruption by laser.

In recognition of the above technical problem and based on the investigation of the distinct properties of the various lens regions and the laser pulse parameters on the generation and spreading of cavitation bubbles, the techniques, apparatus and systems described in this application can be used to effectively fragment the crystalline lens by laser pulses with reduced interference from the bubbles induced by preceding laser pulses. Subsequently, the removal of a portion of or the entirety of the crystalline lens can be achieved via aspiration with reduced or no need of other lens fragmentation or modification techniques.

FIG. 3 illustrates that the hard lens region 109 with different transport, optical and biomechanical properties has significant implications for the photodisruptive fragmentation techniques. One significant limitation of the various laser-based lens fragmentation techniques is the hard-to-control spread of gas bubbles that may occur during the photodisruption that can reduce the effectiveness of the subsequent laser pulses to carry out their intended function.

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FIG. 3A illustrates that a laser beam 110, which is focused to a small focal or target area can generate a small gas bubble 111.

FIG. 3B illustrates that the resistance against the spread of this cavitation bubble 111 can vary from layer to layer of the lens 100. Inside the nucleus 101, the small bubble 111 may simply expand into a bigger bubble 112. It may also generate shockwaves around the bubble, as shown at 114. Moreover, if the expanding bubble reaches the nucleus-cortex boundary, as bubble 116 does, then the gas can expand extensively in the softer cortex region 103. Any of these extended gaseous bubbles can disturb, absorb, scatter or even block the subsequent laser pulses, directed to fragment the hard lens region.

In addition, there may be pre-existing channels in the hard lens region that may allow the generated gas to move into the softer lens regions and interfere with further pulse delivery. Such channels may be located along suture lines, where lens fibers meet. Avoidance of these and adjacent areas may also be employed to reduce gas spread. In addition, pulse properties may be modified in these areas to further reduce gas spread. Such areas can be identified preoperatively or alternatively, intra-operative identification of such channels can allow the procedure to be altered.

Methods, which first attempt to remove the softer peripheral layers, including the cortex 103 and attempt to remove the harder nucleus 101 afterwards, face considerable drawbacks, because the initial removal of the peripheral layers may leave behind a disrupted, unclear optical path, making the subsequent fragmentation of the harder nucleus 101 by lasers difficult.

It is noteworthy that laser-disruption techniques developed for other areas of the eye, such as the cornea, cannot be practiced on the lens without substantial modification. One reason for this is that the cornea is a highly layered structure, inhibiting the spread and movement of bubbles very efficiently. Thus, the spread of bubbles poses qualitatively lesser challenges in the cornea than in the softer layers of the lens including the nucleus itself.

The resistance of the various lens regions against the spreading of the gas bubbles 111 depends on numerous individual characteristics of each patient including the age of the patient. The spread of gas can also be influenced by the particular laser parameters applied to the target.

FIG. 4 illustrates an implementation of a photo-disruptive eye-surgical process 200 developed from the above considerations.

FIGS. 5A-K illustrate various embodiments of the method of FIG. 4.

In step 210 a boundary 252 of the hard lens region 109 may be determined from measuring a mechanical or optical characteristic of the lens 100. Implementations may include this step 210 because if the laser pulses are applied outside the hard lens region 109, the generated bubbles may expand considerably and in a hard-to-control manner. Therefore, some implementations may include first a determination of the boundary of the hard lens region 109 so that the laser pulses can be focused inside the hard lens region 109.

FIG. 6 shows an implementation of step 210 based on mechanical characteristics of the bubbles. A string of probe-bubbles 290 may be generated in the lens 100, for example, substantially parallel with a main axis of the eye, separated by a suitable distance, such as 10 to 100 microns. Other bubble strings can be generated in other areas of the lens. As shown, since the harder nucleus 101 shows more resistance against the expansion of the probe-bubbles, the probe-bubbles 290-1 inside the hard nucleus 101 may expand

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slower. By the same token, the cortex 103 may exert less resistance against the expansion of the bubbles and thus the probe-bubbles 290-2 outside the nucleus 101, in the cortex 103 may expand faster. A portion of the boundary 252 between the nucleus 101 and the cortex 103 can then be identified as the line or region separating slow-expanding probe-bubbles 290-1 from fast-expanding probe-bubbles 290-2.

The expansion of the probe-bubbles 290 and the line separating the slow-expanding probe-bubbles 290-1 from the fast-expanding probe-bubbles 290-2 may be observed and tracked by an optical observation method. Many such methods are known, including all kinds of imaging techniques. Mapping out or otherwise recording these separation points or lines can be used to establish the boundary 252 between the softer lens regions and the hard lens region 109. This implementation of step 210 can be pre-operative, i.e. performed prior to the surgical procedure, or intra-operative, i.e. performed as an early phase of the surgical procedure.

Several other methods can be applied for step 210 as well. For example, optical or structural measurements can be performed prior to the surgical procedure on the patient. Or, some database can be used, which correlates some other measurable characteristic of the eye to the size of the nucleus, e.g. using an age-dependent algorithm. In some cases an explicit calculation can be employed as well. In some cases even data from cadavers can be utilized. It is also possible to generate the above bubble string, and then apply an ultrasound agitation, and observe the induced oscillation of the bubbles, especially their frequency. From these observations, the hardness of the surrounding tissue can be inferred as well.

In some cases the method of Optical Coherence Tomography (OCT) can be utilized in step 210. Among other aspects, OCT can measure the opacity of the imaged tissue. From this measurement, the size of the bubbles and the hardness of the region can be inferred once again.

Finally, the hard lens region 109 can be selected based on some other consideration, e.g. when only the cataract region is to be removed, or the nucleus is to be sculpted only. All of these methods are within the scope of step 210 of FIG. 4, and are illustrated in FIG. 5A with the dotted line indicating the boundary 252 of the hard lens region 109.

FIG. 4 illustrates that step 220 may include selecting a laser parameter between a disruption-threshold and a spread-threshold. The laser parameters of the laser pulses 110 can be selected to be above the disruption-threshold for generating the photodisruption in the hard lens region 109. The laser parameters can be selected to be below the spread-threshold that creates uncontrolled spreading of the gas produced by the photodisruption.

These disruption- and spread-thresholds can be demonstrated e.g. in the case of the spatial separation between two adjacent target points of the laser pulses. If the generated bubbles are closer than a lower spread-threshold distance, then the bubbles may coalesce, forming a bigger bubble. These larger bubbles are likely to expand faster and in a harder-to-control manner. On the other hand, if the bubbles are farther than the upper disruption-threshold, then they may not achieve the intended photodisruption or fragmentation of the target tissue. In some cases the range of bubble separation between these thresholds can be between 1 micron and 50 microns.

The duration of the laser pulses may also have analogous disruption- and spread-thresholds. In some implementations the duration may vary in the range of 0.01 picoseconds to 50 picoseconds. In some patients particular results were

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achieved in the pulse duration range of 100 femtoseconds to 2 picoseconds. In some implementations, the laser energy per pulse can vary between the thresholds of 1 microJ and 25 microJ. The laser pulse repetition rate can vary between the thresholds of 10 kHz and 100 MHz.

The energy, target separation, duration and repeat frequency of the laser pulses can also be selected based on a preoperative measurement of lens optical or structural properties. Alternatively, the selection of the laser energy and the target separation can be based on a preoperative measurement of the overall lens dimensions and the use of an age-dependant algorithm, calculations, cadaver measurements, or databases.

FIG. 4 illustrates that in step 230 a mechanical property of a posterior portion of the hard lens region can be modified in the proximity of the identified boundary 252 by a photodisruptive procedure.

FIG. 5B illustrates an embodiment of step 230, where a set of bubbles is generated by initial laser pulses 110-1 in a posterior portion 254 of the hard lens region 109, in the proximity of the boundary 252. The modifying the mechanical property may include that the generated bubbles photodisrupt, fragment, or even emulsify the tissue of the posterior portion 254 of the nucleus 101, thus modifying some of its mechanical properties.

FIG. 4 illustrates that in step 240 a mechanical property of a portion anterior to the already modified posterior portion can be modified by a photodisruptive procedure.

FIG. 5C illustrates an embodiment of step 240, where a second set of bubbles are generated by subsequent laser pulses 110-2 in a region 256 which is anterior to the already modified region 254.

In implementations of the method these photodisruptive steps 240 can be repeatedly applied by moving the focal or target region of the laser beam 110 along a direction from the posterior of the hard lens region 109 to the anterior of the hard lens region 109. This sequence of the photodisruptive steps 240 controls and limits the buildup and spread of bubbles in the optical path of the subsequent laser pulses 110-2. These implementations allow the subsequent laser pulses 110-2 to deliver essentially their entire energy to the target area, allow for better control of the subsequent pulses, as well as clearer imaging of the surgical area for the benefit of the person conducting the procedure.

Steps 210-240 may be followed by the removal of the fragmented, disrupted, emulsified or otherwise modified hard lens regions 109, if required or desired. One method of removing the fragmented, disrupted, or otherwise modified regions is to create one or more small openings, or incisions in the lens capsule 105, and then insert an aspiration probe to remove the fragmented material. In other implementations, simple suction can extract the fragmented material, as well as the non-fragmented viscous material, such as the cortex 103, without inserting a probe into the capsule.

When laser pulses are applied to the hard lens region 109 from the posterior to anterior direction, between the disruption- and the spread-thresholds, they can optically modify, photodisrupt, or fragment the structure of the treated hard lens region 109 to facilitate lens material removal while also reducing the spread of gas and bubbles during placement of these initial and subsequent laser pulses. The characteristics of the hard lens region 109 can vary from patient to patient though, thus the disruption-threshold and spread-threshold laser parameters may need to be determined from patient to patient.

In some implementations, the energy of the laser beam can be adjusted as the focal point is moved in the posterior-

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to-anterior direction. To reach the anterior layers, the laser beam passes through less material and thus a laser beam with less energy can achieve the same disruption in the target tissue. Accordingly, applying a laser beam with a constant energy may generate an increasing amount of gas as the laser is moved in the anterior direction. To avoid the generation and subsequent spread of such an excess amount of gas, in some implementations the laser energy can be reduced as the laser is moved in the posterior-to-anterior direction. In other implementations, the applied laser energy can also be adjusted as the laser is scanning in the X-Y transverse direction, as the amount of material the laser passes through also varies as the scanning proceeds in the X-Y transverse direction.

In some implementations, the rate of reduction of the applied energy can be calculated from an imaging procedure, which is sensitive e.g. to an optical density or a scattering of the imaged target tissue.

Additional laser pulses can be applied subsequent to the initial laser application, at target positions in the lens outside the initially treated zone in the central region of the lens. The gas and bubbles created by these subsequent laser pulses can either permeate in the treated central region of the lens without uncontrollably spreading in the lens, or can spread into the lens tissue outside the initially treated zone. As such, the gas produced by photodisruption in the peripheral areas of the lens does not block effective treatment of the hard lens region **109**. The laser treated hard lens region and the peripheral lens material which may or may not be treated with the laser depending on need can be removed from the eye via aspiration, with or without additional lens tissue breakup using mechanical, suction, ultrasonic, laser, heated fluid or other means. In another implementation, only the treated region is removed via aspiration, with or without additional lens tissue breakup using mechanical, suction, ultrasonic, laser, heated fluid or other means.

FIGS. 5D-K illustrate other implementations of the eye surgical method **200**. To set the stage for the description of these methods, a note on terminology. In the following the terminology “an axis of the eye” will be used extensively. There are several ways to define an axis of the eye. The axes of the eye can be categorized e.g. according to the Grand Y. L. Physiological Optics (Springer-Verlag, New York, 1980) as follows:

Optical axis: Line passing through the optical center of the cornea and the lens;

Visual axis: Line passing from the point of fixation to the image on the center of the retina called fovea;

Line of Sight: Line passing from the object point through the center of the entrance of the pupil; and

Pupillary axis: Line passing perpendicularly through the center of the cornea and the center of the entrance of the pupil.

In practice these axes are often quite close to each other. Further, compromise axes can be defined as well, e.g. an axis which lies between any two or three of the above axes. In the rest of this disclosure the scope of the term “the axis of the eye” will include any one of these definitions. The axis of the eye will be also referred to as the Z axis. In typical implementations the laser beam can also be oriented along the Z axis. However, other implementations where the laser beam makes an angle with the Z axis are also within the scope of the described method. The two directions transverse to the Z axis will be sometimes termed X and Y axes, following customary terminology.

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General aspects of these implementations include the following.

First, these implementations benefit from the recognition that a primary source of the biomechanical strength of the lens is based on its fibers. As described above, the fibers are an elongated, hardened, essentially transparent tissue within the lens, which grow around the center of the eye in a somewhat irregular manner, typically starting from the equatorial plane. The length of fibers can vary widely. In some cases the length falls within the range of 1-10 mm. However, fiber lengths outside this range can also occur. The fibers can be joined at sutures. In various contexts the fiber structure of the lens has been described as layered, as an onion structure and as a ball of yarn. Close to the axis of the eye, the fiber layers are typically oriented in a manner near perpendicular, or transverse, to the axis.

The fiber-rich central region forms the nucleus. Accordingly, to a considerable degree the biomechanical strength of the nucleus is provided by the fibers and their layers, which are near perpendicular/transverse to the axis of the eye.

Second, as described below in more detail, there is an improved understanding of the dynamics and expansion of the laser generated cavitation bubbles which make up the incision, indicating that they expand quite differently parallel and transverse to the fiber layers in the lens. Implementations of the surgical methods exploit these differences to improve the efficiency and control of the surgical process.

Third, these implementations also benefit from the availability of new and improved eye-surgical laser systems, which are capable of scanning a large fraction of the surgical area, in some cases the entire area, without repositioning. As described below, this feature may offer substantial positive aspects.

In the light of the above described three developments, some implementations of the eye surgical method differ from existing methods at least in the following aspects:

(i) The Incisions are Non-Transverse:

Close to the center of the eye incisions maybe positioned and oriented in directions which are non-transverse to the axis of the eye. Accordingly, the extent of the incisions can be long along the Z axis and smaller in the X-Y plane.

In some embodiments, the incisions can be essentially parallel to the axis of the eye. Examples include cylinders, whose axis is essentially parallel to the axis of the eye. In some cases the length of the cylinder can be between 0.5 mm to 12 mm in the Z direction and the extent in the X-Y plane, essentially the thickness of the incision, can be in the range of 0.1-500 microns.

A shared characteristic of some of these embodiments is that the individual incisions or features have a longer spatial extent in the Z direction, or axis-parallel direction, than in the X-Y direction, or transverse direction. In the case of e.g. cylindrical incisions (see below), the length of the cylinder along the Z axis is longer than the thickness of its wall in the

X-Y direction. The term “extent in the X-Y direction” will be used to refer to that of the single incision itself, such as its thickness, and not an overall dimension of the geometric form of the incision, e.g. the diameter of a cylinder. In some embodiments, the spatial extent of the incisions in the Z direction can be in the range of 0.5-10 mm, the extent in the X-Y direction, i.e. the X-Y thickness can be in the range of 1-500 microns, and the X-Y diameter of the incision can be in the range of 2-10 mm. The spatial extent of the individual incisions can be chosen depending on the number of parallel incisions and their separation.

Other embodiments can be practiced as well, where the incisions make some angle with the axis of the eye, e.g. in

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the form of a cone, or a tilted cylinder, or any other form, non-transverse to the axis of the eye. Non-transverse incisions with piece-wise transverse sections are also within the scope of these implementations.

(ii) The Incisions Cut Fibers:

Close to the axis of the eye, because of the non-transverse orientation of the incisions, the incisions cut through some of the fibers of the lens, as the fibers and their layers are typically close to transverse to the axis of the eye. In peripheral areas of the lens the fibers and their layers tilt/bend away from the transverse direction. Accordingly, in these peripheral regions the incisions themselves can be oriented in a direction which still cuts the non-transverse fibers. Since the fibers are a primary source of the biomechanical strength of the lens, cutting through the fibers reduces the biomechanical strength of the lens effectively.

(iii) The Orientation of the Incision Offers Superior Gas Management:

The impact of the laser beam creates minuscule bubbles in the target tissue. Experiments reveal that these bubbles undergo a two stage expansion. During an initial fast expansion, the bubbles may expand at supersonic speeds, and thus can be very efficient at fragmenting/disrupting the surrounding tissue. This fast expansion is typically anisotropic and occurs mostly in the direction of the laser beam, i.e. approximately the Z direction. The second stage of the expansion is slower, and typically occurs towards the softer tissue, i.e. between the fiber layers, in the transverse direction. During this slow transverse expansion, bubbles often coalesce into bigger bubbles, which can obscure the optical path of subsequent laser pulses, considerably undermining the control and efficiency of the procedure.

In existing methods, which create transverse incisions, the fast, Z-directional bubble expansion does not help creating the transverse incision, and therefore the surgeon has to create the bubbles much more closely to each other.

In contrast, in implementations of the present method, creating incisions approximately in the Z direction, the anisotropy of the fast bubble expansion is put to good use, as it allows the surgeon to create fewer bubbles spaced farther apart in the Z direction, since the bubbles will fast expand in the Z direction and fragment the tissue between neighboring bubbles efficiently.

Such a reduction of the necessary number of bubbles or the equivalent reduction of laser energy in the present method is a critical difference, as most of the laser beam, after having left the lens, reaches the retina. The retina, being a photosensitive tissue, may suffer substantial damage because of the impact of this laser beam. To achieve a fast and substantial fragmentation of the lens tissue, the energy of the laser is often chosen to be close to values which can damage the retina. Therefore, the reduction of the necessary number of bubbles or the energy per pulse of the laser in the present method can mean the difference between damaging the retina and leaving it intact.

Furthermore, the present method also offers advantages regarding the second, slower bubble expansion. During this stage the bubbles expand in the transverse direction. As described above, these bubbles, especially when coalescing together, can substantially and disadvantageously obscure the target area, reducing the efficiency and control of the surgical procedure.

In the present method, the surgeon can create the Z-directed incisions layer-by-layer (see FIG. 5F-F'-F''), creating only lines of bubbles in each layer. Therefore, the surgeon can move the focus of the laser faster than the transverse expansion of the previously created bubbles.

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In contrast, existing methods create transverse incisions, i.e. the surgeon has to create bubbles covering entire areas, returning repeatedly to regions which have been passed earlier. In these methods it is hard or near impossible for the surgeon to move the laser faster than the expanding bubbles, or to avoid returning to previously impacted areas. In fact the surgeon is regularly forced to operate in the area obscured by the expanding bubbles, leading to a considerable reduction of precision and control over the surgical procedure.

(iv) The Incisions Avoid Sutures in Some Implementations:

As mentioned before, fibers typically come together, or end, in sutures. These sutures often form planar structures, parallel to the Z axis. It has been observed that in some cases bubbles expand particularly fast along sutures. Such a too-fast expansion may result in obscuring or clouding the optical path even if Z directional incisions are formed, thus possibly reducing control and precision. Therefore, some implementations of the method create incisions away from sutures.

At the same time, other implementations may be based on the observation that the sutures provide a structural framework for the fibers, and thus cutting through the sutures may be particularly effective in reducing the biomechanical stability of the lens. This benefit has to be weighed against the above mentioned drawback of fast-expanding bubbles along the sutures. Depending on the comparative cost-benefit analysis and the other requirements of the method, some implementations may avoid making incisions at or near the sutures, while others may cut through some of the sutures.

(v) Making Fewer Incisions Applies Less Energy to the Eye:

Since the fiber-cutting incisions are quite efficient in reducing the biomechanical strength of the lens, a reduced number of incisions are capable of achieving the extent of tissue fragmentation necessary for the objectives of the eye surgery. Reduced number of incisions can be applied in shorter time, thereby applying less energy to the eye. Therefore, these surgical methods deposit a reduced amount of energy in the eye, thus e.g. reducing the potential risk to light sensitive tissue, such as the retina by this method.

In some implementations, an eye surgical method making transverse incisions may require 150-160 seconds to achieve the fragmenting of the lens to the degree which is reached in only 45-50 seconds with methods which make essentially axis-parallel incisions.

This factor of 3-4 reduction of surgery time can be quite beneficial, since often surgical patients develop hard-to-control eye movements after about 120 seconds, necessitating the abandonment of the surgical procedure. The just-described reduction of surgery time can mean the difference between the successful completion of the surgery and its abandonment.

Equivalently, this time reduction can be converted into reducing the energy deposited by the laser by a factor of 3-4 in fiber-cutting methods during comparable surgery times, thereby substantially reducing the potential for damage in the retina.

(vi) Incisions are Few and Extended:

The eye surgical method can be performed with surgical instruments which are configured to create incisions with unprecedented spatial extent. In some implementations of the surgical instrument this extent can be 0.5-10 mm in the Z direction, in some cases 2-4 mm, and 2-8 mm in the X-Y

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plane. This large spatial extent of the incisions imparts several positive features to the surgical method, as described below.

(vii) Extended Incisions have Fewer Acceleration/Deceleration Regions:

When making an individual incision, at the beginning of the incision the movement of the laser-focal-point typically accelerates from zero to the regular scanning speed. While the laser is accelerating, it may deposit energy at a higher rate or higher density to the eye, possibly leading to damage in the light sensitive tissues, such as the retina. The same applies at the end of incisions, when the laser-focal-point is decelerating, again possibly damaging the retina. Therefore, methods which utilize longer incisions reduce the number of acceleration/deceleration regions, thus reducing the potential for damage to the light sensitive tissues in these regions in contrast to methods which use a large number of minute incisions.

Existing surgical systems are unable to avoid this problem, as their scanning range in the Z and X-Y directions is considerably less than the entire surgical region. In some existing systems the X-Y scanning range can be 1-2 mm and the Z scanning range can be 0.5 mm, which is substantially less than the entire surgical region of the lens, such as the size of the nucleus. Typically, the nucleus has a Z extent of 2-4 mm and an X-Y diameter of 6-10 mm. This limitation of the existing systems requires that the surgeon make a large number of smaller incisions, with lots of acceleration/deceleration regions. Once the laser scanner reaches its maximum range when making an incision, the surgeon has to stop the scanning via a deceleration, then reposition the laser scanner pointing to a new scan-start point and start a new incision with an acceleration region. Thus methods using existing laser surgical systems involve creating a number of acceleration/deceleration regions, with the concomitant problems.

In contrast, implementations of the present method may benefit from the availability of improved laser systems, which can have a considerably extended X-Y scanning range of 2-10 mm and Z range of 0.5-10 mm. Therefore, implementations of the present method may involve making only a few incisions, thus generating only few of the problematic acceleration/deceleration regions.

In particular, some surgical laser systems may be capable of scanning the entire surgical region. With such systems, the lens-surgery may involve creating only one, uninterrupted extended incision, thus having the lowest possible number of acceleration/deceleration regions.

Here it is mentioned that surgical laser systems with larger X-Y scanning ranges have been described before. However, these systems were used for surgery on the cornea. There are crucial differences between lens surgery and cornea surgery, as during lens surgery both the imaging light off the target and the applied laser propagate through optically active regions: the cornea, the antechamber and part of the lens itself. Propagation through these regions deflects the light substantially both because their differing index of refraction as well as their varying curvature. Therefore, considerable corrections and calculations are required by the surgical equipment and its operator to point the laser to its indented target region.

Further, the laser beam needs to be not only pointed but also focused on the target. A convergent beam is, by definition, extended off its focus point, or target. Therefore, prior to reaching the target, different sections of the converging

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laser beam propagate through regions of the eye with different optical properties and different curvatures, posing a second level of challenges.

In contrast, the cornea is the outermost optically active layer of the eye. Therefore, neither the pointing nor the focusing of the laser beam poses a hard challenge. Further, the problems arising from the curvature of the cornea can be minimized e.g. by applanating it, i.e. making the cornea essentially flat by applying various contact lenses and devices. In contrast, applanating the lens is quite challenging and presently no proposal is available how to achieve this.

Because of all the described hard challenges, corneal surgical laser systems are qualitatively simpler than lens surgical lasers. This is well supported by the fact that even though corneal surgical systems were suggested about 40 years ago, none have been adapted successfully for lens surgery to date.

(viii) Extended Incisions Pose Less Stringent Requirements for Synchronization:

Surgical lasers typically have a beam controller, configured to switch the laser beam on and off, or control the laser via a shutter mechanism. This beam controller is synchronized with the beam scanner as the laser is switched off when the beam scanner reaches its maximum range, or the end of the incision intended by the surgeon. These surgeries require synchronization between the beam scanner, the beam controller and the surgeon's actions. In surgical methods which employ a large number of small incisions, this need for synchronization poses stringent requirements on the beam controller and beam scanner. In contrast, surgical methods which employ few and extended incisions impose considerably less stringent synchronization requirements.

(ix) Extended Incisions have Fewer Transient Laser Fronts:

When the laser is switched on to start a new incision, the initial front of the laser may have transients which are less-well-controlled. These laser fronts may carry a less-well-controlled amount of energy and may be less well focused on the intended target region. Surgical methods using longer incisions and thus employing fewer switch on/off events reduce the number of such less-well-controlled laser fronts and transients, increasing the control over the tissue fragmentation.

(x) Extended Incisions Minimize Z-Scanner Movement:

Minimizing speed and the acceleration of the scanner mechanism along the Z axis is particularly important because the limits of speed and acceleration along the Z axis are more stringent than along the X and Y axes. While scanning in the transverse X-Y direction is achieved in some embodiments by rotating small and light scanning mirrors, Z axis scanning customarily involves translating a lens or a lens group of the delivery system linearly along the optical axis. This lens or lens group is usually heavier than the scanning mirrors and thus has a higher inertia. Therefore, moving this lens or lens group fast can be more difficult than moving the X-Y scanning mirrors. Extended incisions place less demanding requirements on the movement of the Z-scanner.

Aspects (vi) to (x) highlight that eye surgical systems which are capable of scanning the laser beam in a more extended range and thus are capable of making longer incisions without repositioning, offer substantial positive aspects over systems which are capable of shorter incisions only.

In particular, laser scanners which can scan the laser beam across the entire surgical region without interruption or

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repositioning can avoid most of the deficiencies of prior systems, which require such repositioning, as described in points (vi)-(x).

In some implementations the laser pulses can be applied with laser-parameters which are sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye.

Because of the enhanced efficiency of the incisions in the above described surgical method to weaken the biomechanical properties of the lens, in some implementations the laser pulses can be applied with laser-parameters which would have been insufficient to fragment the lens to a degree suitable for removal, had the pulses been used to form an incision transverse to the axis of the eye.

Laser parameters in various implementations may fall into this “insufficient-to-fragment” range if a laser pulse energy is in the range of 0.5 microJ to 50 microJ, a duration of a laser pulse is in the range of 0.005 picoseconds to 25 picoseconds, a repetition rate of applying laser pulses is in the range of 1 kHz to 10 MHz, and a separation distance of target regions of laser pulses is in the range of 1 micron to 100 microns.

For all the above reasons, laser-formed incisions which are dominantly non-transverse to the visual axis and thus cut through layers of lens fibers, weaken the biomechanical strength of the lens qualitatively more efficiently than incisions which are transverse to the axis and thus cut only few fibers or none at all. Therefore, implementations of this method require considerably less power, shorter application time or lower repetition rate for the surgical laser pulses. Due to this efficiency of these implementations, the treatment times to fragment the lens can be reduced by a factor of 3-4 or more. Further, implementations benefit in a multiplicity of ways from new and improved surgical systems which allow the scanning of the entire surgical region without interruption or repositioning.

FIGS. 5D-K illustrate various implementations of the surgical method. The surgical method may start with the surgeon selecting a surgical region of the eye to be treated. Next, the surgeon may design the procedure by selecting the location of the non-transverse incisions to be made. Then, the surgeon can form non-transverse incisions in the surgical region by the fast and repeated application of laser pulses. During the application of the laser pulses, the focus of the laser pulses can be moved in a posterior to anterior direction so that the previously formed bubbles do not obscure the target region the subsequent laser pulses are to be applied.

FIGS. 5D-K illustrate various incisions in the lens 100, created by various implementation of the surgical method.

FIGS. 5D-D' illustrate dominantly transverse incisions, formed by a large number of bubbles generated in transverse layers. These incisions will also be referred to as transverse incisions. FIG. 5D illustrates the layers of bubbles which make up the transverse layers 260-i from the side, highlighting the X-Z plane of the lens. FIG. 5D' illustrates the same from the top, highlighting the X-Y plane.

FIGS. 5E-E' illustrate a dominantly axis-parallel or Z-directional cylindrical incision. FIG. 5E illustrates the bubbles which make up concentric axis-parallel cylinders 262-i from the side, highlighting the X-Z plane of the lens. The bubbles are shown only on the outermost cylinder for clarity. FIG. 5E' illustrates the same from the top, highlighting the X-Y plane. While in typical implementations the bubbles are densely packed, the figures show the bubbles only sparsely and on selected cylinders to avoid clutter. As described above, analogous implementations can utilize any related geometrical form which is non-transverse to the optical axis,

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including incisions of the form of a cone, tilted cylinder, bulging or bending shape. These incisions typically cut through the fibers of the lens.

FIGS. 5F-F'' illustrate steps of generating several cylindrical incisions. This particular implementation involves three cylinders, but others may involve any number of cylinders which are capable of achieving the surgical goal, e.g. the photodisruption of the lens.

In some implementations the cylinders are formed layer-by-layer simultaneously, i.e. in parallel. These implementations face less of a problem regarding the subsequent laser targeting being hindered by the expansion of the earlier formed bubbles.

To start with, the surgeon may decide the posterior-most depth of the incisions. A guiding principle may be to make sure that the incision is safely within the lens, and therefore the capsule is not accidentally pierced by the method, leading to undesirable consequences.

Then the surgeon may apply laser pulses to form a ring of bubbles with a diameter of e.g. the outermost cylinder 262-1, to form the posterior-most ring of cylinder 262-1. When the laser focal point is moved along the entire ring and arrives back to the starting point SP, the surgeon may move the focus of the laser along connector-line 263-1 towards the center until it reaches the next cylinder 262-2. The focus of the laser is then moved again to form the posterior-most ring of cylinder 262-2. Finally, again using the connector-line 263-1, the posterior-most ring of the innermost cylinder 262-3 is formed the same way.

An aspect of this method is that all these steps were carried out by continuously applying the laser, in effect creating one incision. Therefore, at no time is the surgeon forced to switch off the laser beam, thus avoiding the problems described in points (vi)-(x) above. In other implementations more than one incision is made, but still only a few of them, and not a large number of minute incisions.

Next, the surgeon can move the focus of the laser in a posterior-to-anterior direction, and start forming the second layer of rings of the three cylinders 262-1, . . . 262-3. Thus, layer-by-layer, the three cylinders 262-1, . . . 262-3 can be formed essentially simultaneously.

In the implementation of FIG. 5F, the connector-lines 263 are aligned in different ring-layers.

FIGS. 5F'-5F'' illustrate a different implementation, where the connector lines are not aligned in different layers. Visibly, the connector lines 263-1, . . . , 263-3 in ring layers 1, 2, 3 can be rotated relative to each other. For clarity the connector lines in the lower layers are shown with dotted lines.

These implementations simplify the scanning pattern of the pulses and avoid the need for special measures to block or turn off the laser while moving from one incision to another. In such cases, the effectiveness of the fragmentation by the incisions may be further enhanced by the alternation of the position and/or orientation of the connecting segments.

FIGS. 5G-G' illustrate a Cross Plane embodiment. FIG. 5G illustrates one of the two cross planes 265-1 from the side, highlighting the X-Z plane of the lens. The central column of bubbles shown with bold lines indicates the other of the two cross planes 265-2, pointing out from the X-Z plane.

FIG. 5G' illustrates the same two cross planes 265-1 and 265-2 from the top, highlighting the X-Y plane.

In practice, these two cross planes again can be formed by a layer-by-layer approach, i.e. forming the posterior-most row of bubbles of cross plane 265-1, then move the focal

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point of the laser along an arc to the starting point of the posterior-most row of the other cross plane 265-2 and form that row. As the cross-planes are being formed layer-by-layer, the arcs can form a cylinder around the cross planes. In this sense, this implementation creates an integrated cross-plane/cylinder structure.

A large number of variations and combinations of the above implementations are possible.

FIG. 5H illustrates that e.g. instead of two cross planes 3, 4, 6, etc cross planes 265-i can be created, forming “slices” or “wedges” of the cylindrical surgical region.

FIG. 5I illustrates a spiral shaped incision 267, where no large angle redirection is involved in the formation of the incision.

FIG. 5I' illustrates a multi-layer spiral incision. In this implementation when a spiral incision 267-1 is completed in a first, posterior layer, the surgeon can move the focal point of the surgical laser to the central starting point of the spiral in a second, anterior layer following a smooth and gently rising connecting line 268, and then start creating the spiral 267-2 in this second anterior layer. This smooth connecting line 268, indicated by the solid dots, can be an approximate semi-circle, or any one of a large number of similarly smooth curves. Such smooth connecting lines reduce the acceleration of the focal point, providing for a more even application of laser energy into the target tissue.

FIGS. 5J-J' illustrate that the focal plane 271 is typically curved in optical systems unless (any suitable portion of) the optics 273 of the laser delivery system is corrected for field curvature. In most uncorrected optical systems the curvature is positive, i.e. the focal length is longer for axial beams 275-1 and shorter for off-axis beams 275-2, as shown in FIG. 5J.

When the intended incision is a straight transverse line or and extended transverse planar cut, the servo motor driving the Z-scanner (the “Z servo”) can be continuously adjusted in order to compensate the distorting effect of field curvature. However, since the transverse X-Y scanning speed may be much higher than the Z scanning speed because of the higher inertia associated with the Z scanning, the Z servo may not be able to adjust the focus of the laser beam in the Z direction at the high speed of the X-Y scanner.

FIG. 5J' illustrates an implementation which does not require adjusting the Z-scanner at the X-Y transverse scanning rate. In this implementation an incision 276 is formed which follows the curvature of the focal plane 271 of the laser delivery optics 273. The incision 276 can be any of the previously described non-transverse lines, non-transverse planar cuts, layers of spirals, nested cylinders or crossed planes. When any of these implementations are formed on a layer-by-layer basis, the incisions in several or all of the layers may follow the curvature of the focal plane 271, thus reducing or eliminating the need to move the Z servo at the rate of the X-Y scanner. Therefore, these implementations can be operated at the fast X-Y transverse scanning speed instead of the slower Z-scanning speed.

In yet other various embodiments the incisions can take a wide variety of shapes including straight planes, curved planes, cones, tilted cylinders, any type of shapes which are not transverse to the z axis, incisions which have portions which are transverse to the z axis, various crossing patterns and any combination of these patterns. Such shapes can be connected by interconnecting planes that further fragment the lens tissue, while also potentially easing the delivery of laser pulses by reducing the need to shutter the laser or make large movements with the scanning system.

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After cutting the fibers by the laser-formed incisions, the cut fibers can be removed with a variety of techniques, including hydro-dissection, manual fragmentation, the application of ultrasound, aspiration, or a combination of these or other methods.

FIG. 5K illustrates yet another composite implementation. In this implementation, a shield layer 280 can be implemented in the posterior-most region of the lens, to a substantial degree transverse to the axis of the eye. One of the functions of this protection layer 280 is to protect the retina from the negative effects of the laser irradiation used for forming the incisions 262-i.

FIGS. 7-26 illustrate embodiments of a laser surgery system in relation to the above photodisruptive laser treatment.

One important aspect of laser surgical procedures is precise control and aiming of a laser beam, e.g., the beam position and beam focusing. Laser surgery systems can be designed to include laser control and aiming tools to precisely target laser pulses to a particular target inside the tissue. In various nanosecond photodisruptive laser surgical systems, such as the Nd:YAG laser systems, the required level of targeting precision is relatively low. This is in part because the laser energy used is relatively high and thus the affected tissue area is also relatively large, often covering an impacted area with a dimension in the hundreds of microns. The time between laser pulses in such systems tend to be long and manual controlled targeting is feasible and is commonly used. One example of such manual targeting mechanisms is a biomicroscope to visualize the target tissue in combination with a secondary laser source used as an aiming beam. The surgeon manually moves the focus of a laser focusing lens, usually with a joystick control, which is parfocal (with or without an offset) with their image through the microscope, so that the surgical beam or aiming beam is in best focus on the intended target.

Such techniques designed for use with low repetition rate laser surgical systems may be difficult to use with high repetition rate lasers operating at thousands of shots per second and relatively low energy per pulse. In surgical operations with high repetition rate lasers, much higher precision may be required due to the small effects of each single laser pulse and much higher positioning speed may be required due to the need to deliver thousands of pulses to new treatment areas very quickly.

Examples of high repetition rate pulsed lasers for laser surgical systems include pulsed lasers at a pulse repetition rate of thousands of shots per second or higher with relatively low energy per pulse. Such lasers use relatively low energy per pulse to localize the tissue effect caused by laser-induced photodisruption, e.g., the impacted tissue area by photodisruption on the order of microns or tens of microns. This localized tissue effect can improve the precision of the laser surgery and can be desirable in certain surgical procedures such as laser eye surgery. In one example of such surgery, placement of many hundred, thousands or millions of contiguous, nearly contiguous or pulses separated by known distances, can be used to achieve certain desired surgical effects, such as tissue incisions, separations or fragmentation.

Various surgical procedures using high repetition rate photodisruptive laser surgical systems with shorter laser pulse durations may require high precision in positioning each pulse in the target tissue under surgery both in an absolute position with respect to a target location on the target tissue and a relative position with respect to preceding pulses. For example, in some cases, laser pulses may be

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required to be delivered next to each other with an accuracy of a few microns within the time between pulses, which can be on the order of microseconds. Because the time between two sequential pulses is short and the precision requirement for the pulse alignment is high, manual targeting as used in low repetition rate pulsed laser systems may be no longer adequate or feasible.

One technique to facilitate and control precise, high speed positioning requirement for delivery of laser pulses into the tissue is attaching a applanation plate made of a transparent material such as a glass with a predefined contact surface to the tissue so that the contact surface of the applanation plate forms a well-defined optical interface with the tissue. This well-defined interface can facilitate transmission and focusing of laser light into the tissue to control or reduce optical aberrations or variations (such as due to specific eye optical properties or changes that occur with surface drying) that are most critical at the air-tissue interface, which in the eye is at the anterior surface of the cornea. Contact lenses can be designed for various applications and targets inside the eye and other tissues, including ones that are disposable or reusable. The contact glass or applanation plate on the surface of the target tissue can be used as a reference plate relative to which laser pulses are focused through the adjustment of focusing elements within the laser delivery system. This use of a contact glass or applanation plate provides better control of the optical qualities of the tissue surface and thus allow laser pulses to be accurately placed at a high speed at a desired location (interaction point) in the target tissue relative to the applanation reference plate with little optical distortion of the laser pulses.

One way for implementing an applanation plate on an eye is to use the applanation plate to provide a positional reference for delivering the laser pulses into a target tissue in the eye. This use of the applanation plate as a positional reference can be based on the known desired location of laser pulse focus in the target with sufficient accuracy prior to firing the laser pulses and that the relative positions of the reference plate and the individual internal tissue target must remain constant during laser firing. In addition, this method can require the focusing of the laser pulse to the desired location to be predictable and repeatable between eyes or in different regions within the same eye. In practical systems, it can be difficult to use the applanation plate as a positional reference to precisely localize laser pulses intraocularly because the above conditions may not be met in practical systems.

For example, if the crystalline lens is the surgical target, the precise distance from the reference plate on the surface of the eye to the target tends to vary due to the presence of collapsible structures, such as the cornea itself, the anterior chamber, and the iris. Not only is their considerable variability in the distance between the applanated cornea and the lens between individual eyes, but there can also be variation within the same eye depending on the specific surgical and applanation technique used by the surgeon. In addition, there can be movement of the targeted lens tissue relative to the applanated surface during the firing of the thousands of laser pulses required for achieving the surgical effect, further complicating the accurate delivery of pulses. In addition, structure within the eye may move due to the build-up of photodisruptive byproducts, such as cavitation bubbles. For example, laser pulses delivered to the crystalline lens can cause the lens capsule to bulge forward, requiring adjustment to target this tissue for subsequent placement of laser pulses. Furthermore, it can be difficult to use computer models and simulations to predict, with sufficient accuracy,

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the actual location of target tissues after the applanation plate is removed and to adjust placement of laser pulses to achieve the desired localization without applanation in part because of the highly variable nature of applanation effects, which can depend on factors particular to the individual cornea or eye, and the specific surgical and applanation technique used by a surgeon.

In addition to the physical effects of applanation that disproportionately affect the localization of internal tissue structures, in some surgical processes, it may be desirable 10 for a targeting system to anticipate or account for nonlinear characteristics of photodisruption which can occur when using short pulse duration lasers. Photodisruption is a nonlinear optical process in the tissue material and can cause complications in beam alignment and beam targeting. For example, one of the nonlinear optical effects in the tissue material when interacting with laser pulses during the photodisruption is that the refractive index of the tissue material experienced by the laser pulses is no longer a constant but 15 varies with the intensity of the light. Because the intensity of the light in the laser pulses varies spatially within the pulsed laser beam, along and across the propagation direction of the pulsed laser beam, the refractive index of the tissue material also varies spatially. One consequence of this nonlinear refractive index is self-focusing or self-defocusing in the tissue material that changes the actual focus of and shifts the position of the focus of the pulsed laser beam inside the tissue. Therefore, a precise alignment of the pulsed laser beam to each target tissue position in the target tissue may 20 also need to account for the nonlinear optical effects of the tissue material on the laser beam. In addition, it may be necessary to adjust the energy in each pulse to deliver the same physical effect in different regions of the target due to different physical characteristics, such as hardness, or due to 25 optical considerations such as absorption or scattering of laser pulse light traveling to a particular region. In such cases, the differences in non-linear focusing effects between pulses of different energy values can also affect the laser alignment and laser targeting of the surgical pulses.

Thus, in surgical procedures in which non superficial structures are targeted, the use of a superficial applanation plate based on a positional reference provided by the applanation plate may be insufficient to achieve precise laser pulse localization in internal tissue targets. The use of the applanation plate as the reference for guiding laser delivery may 30 require measurements of the thickness and plate position of the applanation plate with high accuracy because the deviation from nominal is directly translated into a depth precision error. High precision applanation lenses can be costly, especially for single use disposable applanation plates.

The techniques, apparatus and systems described in this document can be implemented in ways that provide a targeting mechanism to deliver short laser pulses through an applanation plate to a desired localization inside the eye with 35 precision and at a high speed without requiring the known desired location of laser pulse focus in the target with sufficient accuracy prior to firing the laser pulses and without requiring that the relative positions of the reference plate and the individual internal tissue target remain constant during laser firing. As such, the present techniques, apparatus and systems can be used for various surgical procedures where physical conditions of the target tissue under surgery tend to vary and are difficult to control and the dimension of the applanation lens tends to vary from one lens to another. The 40 present techniques, apparatus and systems may also be used for other surgical targets where distortion or movement of the surgical target relative to the surface of the structure is 45

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present or non-linear optical effects make precise targeting problematic. Examples for such surgical targets different from the eye include the heart, deeper tissue in the skin and others.

The present techniques, apparatus and systems can be implemented in ways that maintain the benefits provided by an applanation plate, including, for example, control of the surface shape and hydration, as well as reductions in optical distortion, while providing for the precise localization of photodisruption to internal structures of the applanated surface. This can be accomplished through the use of an integrated imaging device to localize the target tissue relative to the focusing optics of the delivery system. The exact type of imaging device and method can vary and may depend on the specific nature of the target and the required level of precision.

An applanation lens may be implemented with another mechanism to fix the eye to prevent translational and rotational movement of the eye. Examples of such fixation devices include the use of a suction ring. Such fixation mechanism can also lead to unwanted distortion or movement of the surgical target. The present techniques, apparatus and systems can be implemented to provide, for high repetition rate laser surgical systems that utilize an applanation plate and/or fixation means for non-superficial surgical targets, a targeting mechanism to provide intraoperative imaging to monitor such distortion and movement of the surgical target.

Specific examples of laser surgical techniques, apparatus and systems are described below to use an optical imaging module to capture images of a target tissue to obtain positioning information of the target tissue, e.g., before and during a surgical procedure. Such obtained positioning information can be used to control the positioning and focusing of the surgical laser beam in the target tissue to provide accurate control of the placement of the surgical laser pulses in high repetition rate laser systems. In one implementation, during a surgical procedure, the images obtained by the optical imaging module can be used to dynamically control the position and focus of the surgical laser beam. In addition, lower energy and shot laser pulses tend to be sensitive to optical distortions, such a laser surgical system can implement an applanation plate with a flat or curved interface attaching to the target tissue to provide a controlled and stable optical interface between the target tissue and the surgical laser system and to mitigate and control optical aberrations at the tissue surface.

As an example, FIG. 7 shows a laser surgical system based on optical imaging and applanation. This system includes a pulsed laser 1010 to produce a surgical laser beam 1012 of laser pulses, and an optics module 1020 to receive the surgical laser beam 1012 and to focus and direct the focused surgical laser beam 1022 onto a target tissue 1001, such as an eye, to cause photodisruption in the target tissue 1001. An applanation plate can be provided to be in contact with the target tissue 1001 to produce an interface for transmitting laser pulses to the target tissue 1001 and light coming from the target tissue 1001 through the interface. Notably, an optical imaging device 1030 is provided to capture light 1050 carrying target tissue images 1050 or imaging information from the target tissue 1001 to create an image of the target tissue 1001. The imaging signal 1032 from the imaging device 1030 is sent to a system control module 1040. The system control module 1040 operates to process the captured images from the image device 1030 and to control the optics module 1020 to adjust the position and focus of the surgical laser beam 1022 at the target tissue 101

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based on information from the captured images. The optics module 120 can include one or more lenses and may further include one or more reflectors. A control actuator can be included in the optics module 1020 to adjust the focusing and the beam direction in response to a beam control signal 1044 from the system control module 1040. The control module 1040 can also control the pulsed laser 1010 via a laser control signal 1042.

The optical imaging device 1030 may be implemented to produce an optical imaging beam that is separate from the surgical laser beam 1022 to probe the target tissue 1001 and the returned light of the optical imaging beam is captured by the optical imaging device 1030 to obtain the images of the target tissue 1001. One example of such an optical imaging device 1030 is an optical coherence tomography (OCT) imaging module which uses two imaging beams, one probe beam directed to the target tissue 1001 thought the applanation plate and another reference beam in a reference optical path, to optically interfere with each other to obtain images of the target tissue 1001. In other implementations, the optical imaging device 1030 can use scattered or reflected light from the target tissue 1001 to capture images without sending a designated optical imaging beam to the target tissue 1001. For example, the imaging device 1030 can be a sensing array of sensing elements such as CCD or CMS sensors. For example, the images of photodisruption byproduct produced by the surgical laser beam 1022 may be captured by the optical imaging device 1030 for controlling the focusing and positioning of the surgical laser beam 1022. When the optical imaging device 1030 is designed to guide surgical laser beam alignment using the image of the photodisruption byproduct, the optical imaging device 1030 captures images of the photodisruption byproduct such as the laser-induced bubbles or cavities. The imaging device 1030 may also be an ultrasound imaging device to capture images based on acoustic images.

The system control module 1040 processes image data from the imaging device 1030 that includes the position offset information for the photodisruption byproduct from the target tissue position in the target tissue 1001. Based on the information obtained from the image, the beam control signal 1044 is generated to control the optics module 1020 which adjusts the laser beam 1022. A digital processing unit can be included in the system control module 1040 to perform various data processing for the laser alignment.

The above techniques and systems can be used deliver high repetition rate laser pulses to subsurface targets with a precision required for contiguous pulse placement, as needed for cutting or volume disruption applications. This can be accomplished with or without the use of a reference source on the surface of the target and can take into account movement of the target following applanation or during placement of laser pulses.

The applanation plate in the present systems is provided to facilitate and control precise, high speed positioning requirement for delivery of laser pulses into the tissue. Such an applanation plate can be made of a transparent material such as a glass with a predefined contact surface to the tissue so that the contact surface of the applanation plate forms a well-defined optical interface with the tissue. This well-defined interface can facilitate transmission and focusing of laser light into the tissue to control or reduce optical aberrations or variations (such as due to specific eye optical properties or changes that occur with surface drying) that are most critical at the air-tissue interface, which in the eye is at the anterior surface of the cornea. A number of contact lenses have been designed for various applications and

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targets inside the eye and other tissues, including ones that are disposable or reusable. The contact glass or applanation plate on the surface of the target tissue is used as a reference plate relative to which laser pulses are focused through the adjustment of focusing elements within the laser delivery system relative. Inherent in such an approach are the additional benefits afforded by the contact glass or applanation plate described previously, including control of the optical qualities of the tissue surface. Accordingly, laser pulses can be accurately placed at a high speed at a desired location (interaction point) in the target tissue relative to the applanation reference plate with little optical distortion of the laser pulses.

The optical imaging device 1030 in FIG. 7 captures images of the target tissue 1001 via the applanation plate. The control module 1040 processes the captured images to extract position information from the captured images and uses the extracted position information as a position reference or guide to control the position and focus of the surgical laser beam 1022. This imaging-guided laser surgery can be implemented without relying on the applanation plate as a position reference because the position of the applanation plate tends to change due to various factors as discussed above. Hence, although the applanation plate provides a desired optical interface for the surgical laser beam to enter the target tissue and to capture images of the target tissue, it may be difficult to use the applanation plate as a position reference to align and control the position and focus of the surgical laser beam for accurate delivery of laser pulses. The imaging-guided control of the position and focus of the surgical laser beam based on the imaging device 1030 and the control module 1040 allows the images of the target tissue 1001, e.g., images of inner structures of an eye, to be used as position references, without using the applanation plate to provide a position reference.

In addition to the physical effects of applanation that disproportionately affect the localization of internal tissue structures, in some surgical processes, it may be desirable for a targeting system to anticipate or account for nonlinear characteristics of photodisruption which can occur when using short pulse duration lasers. Photodisruption can cause complications in beam alignment and beam targeting. For example, one of the nonlinear optical effects in the tissue material when interacting with laser pulses during the photodisruption is that the refractive index of the tissue material experienced by the laser pulses is no longer a constant but varies with the intensity of the light. Because the intensity of the light in the laser pulses varies spatially within the pulsed laser beam, along and across the propagation direction of the pulsed laser beam, the refractive index of the tissue material also varies spatially. One consequence of this nonlinear refractive index is self-focusing or self-defocusing in the tissue material that changes the actual focus of and shifts the position of the focus of the pulsed laser beam inside the tissue. Therefore, a precise alignment of the pulsed laser beam to each target tissue position in the target tissue may also need to account for the nonlinear optical effects of the tissue material on the laser beam. The energy of the laser pulses may be adjusted to deliver the same physical effect in different regions of the target due to different physical characteristics, such as hardness, or due to optical considerations such as absorption or scattering of laser pulse light traveling to a particular region. In such cases, the differences in non-linear focusing effects between pulses of different energy values can also affect the laser alignment and laser targeting of the surgical pulses. In this regard, the direct images obtained from the target issue by the imaging device

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1030 can be used to monitor the actual position of the surgical laser beam 1022 which reflects the combined effects of nonlinear optical effects in the target tissue and provide position references for control of the beam position and beam focus.

10 The techniques, apparatus and systems described here can be used in combination of an applanation plate to provide control of the surface shape and hydration, to reduce optical distortion, and provide for precise localization of photodisruption to internal structures through the applanated surface. The imaging-guided control of the beam position and focus described here can be applied to surgical systems and procedures that use means other than applanation plates to fix the eye, including the use of a suction ring which can lead 15 to distortion or movement of the surgical target.

20 The following sections first describe examples of techniques, apparatus and systems for automated imaging-guided laser surgery based on varying degrees of integration of imaging functions into the laser control part of the systems. An optical or other modality imaging module, such as an OCT imaging module, can be used to direct a probe light or other type of beam to capture images of a target tissue, e.g., structures inside an eye. A surgical laser beam of 25 laser pulses such as femtosecond or picosecond laser pulses can be guided by position information in the captured images to control the focusing and positioning of the surgical laser beam during the surgery. Both the surgical laser beam and the probe light beam can be sequentially or simultaneously directed to the target tissue during the surgery so that the surgical laser beam can be controlled based 30 on the captured images to ensure precision and accuracy of the surgery.

Such imaging-guided laser surgery can be used to provide 35 accurate and precise focusing and positioning of the surgical laser beam during the surgery because the beam control is based on images of the target tissue following applanation or fixation of the target tissue, either just before or nearly simultaneously with delivery of the surgical pulses. Notably, certain parameters of the target tissue such as the eye 40 measured before the surgery may change during the surgery due to various factor such as preparation of the target tissue (e.g., fixating the eye to an applanation lens) and the alteration of the target tissue by the surgical operations. Therefore, measured parameters of the target tissue prior to 45 such factors and/or the surgery may no longer reflect the physical conditions of the target tissue during the surgery. The present imaging-guided laser surgery can mitigate technical issues in connection with such changes for focusing and positioning the surgical laser beam before and during the 50 surgery.

The present imaging-guided laser surgery may be effectively used for accurate surgical operations inside a target tissue. For example, when performing laser surgery inside the eye, laser light is focused inside the eye to achieve 55 optical breakdown of the targeted tissue and such optical interactions can change the internal structure of the eye. For example, the crystalline lens can change its position, shape, thickness and diameter during accommodation, not only between prior measurement and surgery but also during 60 surgery. Attaching the eye to the surgical instrument by mechanical means can change the shape of the eye in a not well defined way and further, the change can vary during surgery due to various factors, e.g., patient movement. Attaching means include fixating the eye with a suction ring 65 and applanating the eye with a flat or curved lens. These changes amount to as much as a few millimeters. Mechanically referencing and fixating the surface of the eye such as

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the anterior surface of the cornea or limbus does not work well when performing precision laser microsurgery inside the eye.

The post preparation or near simultaneous imaging in the present imaging-guided laser surgery can be used to establish three-dimensional positional references between the inside features of the eye and the surgical instrument in an environment where changes occur prior to and during surgery. The positional reference information provided by the imaging prior to applanation and/or fixation of the eye, or during the actual surgery reflects the effects of changes in the eye and thus provides an accurate guidance to focusing and positioning of the surgical laser beam. A system based on the present imaging-guided laser surgery can be configured to be simple in structure and cost efficient. For example, a portion of the optical components associated with guiding the surgical laser beam can be shared with optical components for guiding the probe light beam for imaging the target tissue to simplify the device structure and the optical alignment and calibration of the imaging and surgical light beams.

The imaging-guided laser surgical systems described below use the OCT imaging as an example of an imaging instrument and other non-OCT imaging devices may also be used to capture images for controlling the surgical lasers during the surgery. As illustrated in the examples below, integration of the imaging and surgical subsystems can be implemented to various degrees. In the simplest form without integrating hardware, the imaging and laser surgical subsystems are separated and can communicate to one another through interfaces. Such designs can provide flexibility in the designs of the two subsystems. Integration between the two subsystems, by some hardware components such as a patient interface, further expands the functionality by offering better registration of surgical area to the hardware components, more accurate calibration and may improve workflow. As the degree of integration between the two subsystems increases, such a system may be made increasingly cost-efficient and compact and system calibration will be further simplified and more stable over time. Examples for imaging-guided laser systems in FIGS. 8-16 are integrated at various degrees of integration.

One implementation of a present imaging-guided laser surgical system, for example, includes a surgical laser that produces a surgical laser beam of surgical laser pulses that cause surgical changes in a target tissue under surgery; a patient interface mount that engages a patient interface in contact with the target tissue to hold the target tissue in position; and a laser beam delivery module located between the surgical laser and the patient interface and configured to direct the surgical laser beam to the target tissue through the patient interface. This laser beam delivery module is operable to scan the surgical laser beam in the target tissue along a predetermined surgical pattern. This system also includes a laser control module that controls operation of the surgical laser and controls the laser beam delivery module to produce the predetermined surgical pattern and an OCT module positioned relative to the patient interface to have a known spatial relation with respect to the patient interface and the target issue fixed to the patient interface. The OCT module is configured to direct an optical probe beam to the target tissue and receive returned probe light of the optical probe beam from the target tissue to capture OCT images of the target tissue while the surgical laser beam is being directed to the target tissue to perform an surgical operation so that the optical probe beam and the surgical laser beam are simultaneously present in the target tissue. The OCT module

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is in communication with the laser control module to send information of the captured OCT images to the laser control module.

In addition, the laser control module in this particular system responds to the information of the captured OCT images to operate the laser beam delivery module in focusing and scanning of the surgical laser beam and adjusts the focusing and scanning of the surgical laser beam in the target tissue based on positioning information in the captured OCT images.

In some implementations, acquiring a complete image of a target tissue may not be necessary for registering the target to the surgical instrument and it may be sufficient to acquire a portion of the target tissue, e.g., a few points from the surgical region such as natural or artificial landmarks. For example, a rigid body has six degrees of freedom in 3D space and six independent points would be sufficient to define the rigid body. When the exact size of the surgical region is not known, additional points are needed to provide the positional reference. In this regard, several points can be used to determine the position and the curvature of the anterior and posterior surfaces, which are normally different, and the thickness and diameter of the crystalline lens of the human eye. Based on these data a body made up from two halves of ellipsoid bodies with given parameters can approximate and visualize a crystalline lens for practical purposes. In another implementation, information from the captured image may be combined with information from other sources, such as pre-operative measurements of lens thickness that are used as an input for the controller.

FIG. 8 shows one example of an imaging-guided laser surgical system with separated laser surgical system 2100 and imaging system 2200. The laser surgical system 2100 includes a laser engine 2130 with a surgical laser that produces a surgical laser beam 2160 of surgical laser pulses. A laser beam delivery module 2140 is provided to direct the surgical laser beam 2160 from the laser engine 2130 to the target tissue 1001 through a patient interface 2150 and is operable to scan the surgical laser beam 2160 in the target tissue 1001 along a predetermined surgical pattern. A laser control module 2120 is provided to control the operation of the surgical laser in the laser engine 2130 via a communication channel 2121 and controls the laser beam delivery module 2140 via a communication channel 2122 to produce the predetermined surgical pattern. A patient interface mount is provided to engage the patient interface 2150 in contact with the target tissue 1001 to hold the target tissue 1001 in position. The patient interface 2150 can be implemented to include a contact lens or applanation lens with a flat or curved surface to conformingly engage to the anterior surface of the eye and to hold the eye in position.

The imaging system 2200 in FIG. 8 can be an OCT module positioned relative to the patient interface 2150 of the surgical system 2100 to have a known spatial relation with respect to the patient interface 2150 and the target issue 1001 fixed to the patient interface 2150. This OCT module 2200 can be configured to have its own patient interface 2240 for interacting with the target tissue 1001. The imaging system 2200 includes an imaging control module 2220 and an imaging sub-system 2230. The sub-system 2230 includes a light source for generating imaging beam 2250 for imaging the target 1001 and an imaging beam delivery module to direct the optical probe beam or imaging beam 2250 to the target tissue 1001 and receive returned probe light 2260 of the optical imaging beam 2250 from the target tissue 1001 to capture OCT images of the target tissue 1001. Both the optical imaging beam 2250 and the surgical beam 2160 can

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be simultaneously directed to the target tissue **1001** to allow for sequential or simultaneous imaging and surgical operation.

As illustrated in FIG. 8, communication interfaces **2110** and **2210** are provided in both the laser surgical system **2100** and the imaging system **2200** to facilitate the communications between the laser control by the laser control module **2120** and imaging by the imaging system **2200** so that the OCT module **2200** can send information of the captured OCT images to the laser control module **2120**. The laser control module **2120** in this system responds to the information of the captured OCT images to operate the laser beam delivery module **2140** in focusing and scanning of the surgical laser beam **2160** and dynamically adjusts the focusing and scanning of the surgical laser beam **2160** in the target tissue **1001** based on positioning information in the captured OCT images. The integration between the laser surgical system **2100** and the imaging system **2200** is mainly through communication between the communication interfaces **2110** and **2210** at the software level.

In this and other examples, various subsystems or devices may also be integrated. For example, certain diagnostic instruments such as wavefront aberrometers, corneal topography measuring devices may be provided in the system, or pre-operative information from these devices can be utilized to augment intra-operative imaging.

FIG. 9 shows an example of an imaging-guided laser surgical system with additional integration features. The imaging and surgical systems share a common patient interface **3300** which immobilizes target tissue **1001** (e.g., the eye) without having two separate patient interfaces as in FIG. 8. The surgical beam **3210** and the imaging beam **3220** are combined at the patient interface **3330** and are directed to the target **1001** by the common patient interface **3300**. In addition, a common control module **3100** is provided to control both the imaging sub-system **2230** and the surgical part (the laser engine **2130** and the beam delivery system **2140**). This increased integration between imaging and surgical parts allows accurate calibration of the two subsystems and the stability of the position of the patient and surgical volume. A common housing **3400** is provided to enclose both the surgical and imaging subsystems. When the two systems are not integrated into a common housing, the common patient interface **3300** can be part of either the imaging or the surgical subsystem.

FIG. 10 shows an example of an imaging-guided laser surgical system where the laser surgical system and the imaging system share both a common beam delivery module **4100** and a common patient interface **4200**. This integration further simplifies the system structure and system control operation.

In one implementation, the imaging system in the above and other examples can be an optical computed tomography (OCT) system and the laser surgical system is a femtosecond or picosecond laser based ophthalmic surgical system. In OCT, light from a low coherence, broadband light source such as a super luminescent diode is split into separate reference and signal beams. The signal beam is the imaging beam sent to the surgical target and the returned light of the imaging beam is collected and recombined coherently with the reference beam to form an interferometer. Scanning the signal beam perpendicularly to the optical axis of the optical train or the propagation direction of the light provides spatial resolution in the x-y direction while depth resolution comes from extracting differences between the path lengths of the reference arm and the returned signal beam in the signal arm of the interferometer. While the x-y scanner of different

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OCT implementations are essentially the same, comparing the path lengths and getting z-scan information can happen in different ways. In one implementation known as the time domain OCT, for example, the reference arm is continuously varied to change its path length while a photodetector detects interference modulation in the intensity of the recombined beam. In a different implementation, the reference arm is essentially static and the spectrum of the combined light is analyzed for interference. The Fourier transform of the spectrum of the combined beam provides spatial information on the scattering from the interior of the sample. This method is known as the spectral domain or Fourier OCT method. In a different implementation known as a frequency swept OCT (S. R. Chinn, et. al., Opt. Lett. 22, 1997), a narrowband light source is used with its frequency swept rapidly across a spectral range. Interference between the reference and signal arms is detected by a fast detector and dynamic signal analyzer. An external cavity tuned diode laser or frequency tuned of frequency domain mode-locked (FDML) laser developed for this purpose (R. Huber et. Al. Opt. Express, 13, 2005) (S. H. Yun, IEEE J. of Sel. Q. El. 3(4) p. 1087-1096, 1997) can be used in these examples as a light source. A femtosecond laser used as a light source in an OCT system can have sufficient bandwidth and can provide additional benefits of increased signal to noise ratios.

The OCT imaging device in the systems in this document can be used to perform various imaging functions. For example, the OCT can be used to suppress complex conjugates resulting from the optical configuration of the system or the presence of the applanation plate, capture OCT images of selected locations inside the target tissue to provide three-dimensional positioning information for controlling focusing and scanning of the surgical laser beam inside the target tissue, or capture OCT images of selected locations on the surface of the target tissue or on the applanation plate to provide positioning registration for controlling changes in orientation that occur with positional changes of the target, such as from upright to supine. The OCT can be calibrated by a positioning registration process based on placement of marks or markers in one positional orientation of the target that can then be detected by the OCT module when the target is in another positional orientation. In other implementations, the OCT imaging system can be used to produce a probe light beam that is polarized to optically gather the information on the internal structure of the eye. The laser beam and the probe light beam may be polarized in different polarizations. The OCT can include a polarization control mechanism that controls the probe light used for said optical tomography to polarize in one polarization when traveling toward the eye and in a different polarization when traveling away from the eye. The polarization control mechanism can include, e.g., a wave-plate or a Faraday rotator.

The system in FIG. 10 is shown as a spectral OCT configuration and can be configured to share the focusing optics part of the beam delivery module between the surgical and the imaging systems. The main requirements for the optics are related to the operating wavelength, image quality, resolution, distortion etc. The laser surgical system can be a femtosecond laser system with a high numerical aperture system designed to achieve diffraction limited focal spot sizes, e.g., about 2 to 3 micrometers. Various femtosecond ophthalmic surgical lasers can operate at various wavelengths such as wavelengths of around 1.05 micrometer. The operating wavelength of the imaging device can be selected to be close to the laser wavelength so that the optics is

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chromatically compensated for both wavelengths. Such a system may include a third optical channel, a visual observation channel such as a surgical microscope, to provide an additional imaging device to capture images of the target tissue. If the optical path for this third optical channel shares optics with the surgical laser beam and the light of the OCT imaging device, the shared optics can be configured with chromatic compensation in the visible spectral band for the third optical channel and the spectral bands for the surgical laser beam and the OCT imaging beam.

FIG. 11 shows a particular example of the design in FIG. 9 where the scanner 5100 for scanning the surgical laser beam and the beam conditioner 5200 for conditioning (collimating and focusing) the surgical laser beam are separate from the optics in the OCT imaging module 5300 for controlling the imaging beam for the OCT. The surgical and imaging systems share an objective lens 5600 module and the patient interface 3300. The objective lens 5600 directs and focuses both the surgical laser beam and the imaging beam to the patient interface 3300 and its focusing is controlled by the control module 3100. Two beam splitters 5410 and 5420 are provided to direct the surgical and imaging beams. The beam splitter 5420 is also used to direct the returned imaging beam back into the OCT imaging module 5300. Two beam splitters 5410 and 5420 also direct light from the target 1001 to a visual observation optics unit 5500 to provide direct view or image of the target 1001. The unit 5500 can be a lens imaging system for the surgeon to view the target 1001 or a camera to capture the image or video of the target 1001. Various beam splitters can be used, such as dichroic and polarization beam splitters, optical grating, holographic beam splitter or a combinations of these.

In some implementations, the optical components may be appropriately coated with antireflection coating for both the surgical and for the OCT wavelength to reduce glare from multiple surfaces of the optical beam path. Reflections would otherwise reduce the throughput of the system and reduce the signal to noise ratio by increasing background light in the OCT imaging unit. One way to reduce glare in the OCT is to rotate the polarization of the return light from the sample by wave-plate or Faraday isolator placed close to the target tissue and orient a polarizer in front of the OCT detector to preferentially detect light returned from the sample and suppress light scattered from the optical components.

In a laser surgical system, each of the surgical laser and the OCT system can have a beam scanner to cover the same surgical region in the target tissue. Hence, the beam scanning for the surgical laser beam and the beam scanning for the imaging beam can be integrated to share common scanning devices.

FIG. 12 shows an example of such a system in detail. In this implementation the x-y scanner 6410 and the z scanner 6420 are shared by both subsystems. A common control 6100 is provided to control the system operations for both surgical and imaging operations. The OCT sub-system includes an OCT light source 6200 that produce the imaging light that is split into an imaging beam and a reference beam by a beam splitter 6210. The imaging beam is combined with the surgical beam at the beam splitter 6310 to propagate along a common optical path leading to the target 1001. The scanners 6410 and 6420 and the beam conditioner unit 6430 are located downstream from the beam splitter 6310. A beam splitter 6440 is used to direct the imaging and surgical beams to the objective lens 5600 and the patient interface 3300.

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In the OCT sub-system, the reference beam transmits through the beam splitter 6210 to an optical delay device 6220 and is reflected by a return mirror 6230. The returned imaging beam from the target 1001 is directed back to the beam splitter 6310 which reflects at least a portion of the returned imaging beam to the beam splitter 6210 where the reflected reference beam and the returned imaging beam overlap and interfere with each other. A spectrometer detector 6240 is used to detect the interference and to produce OCT images of the target 1001. The OCT image information is sent to the control system 6100 for controlling the surgical laser engine 2130, the scanners 6410 and 6420 and the objective lens 5600 to control the surgical laser beam. In one implementation, the optical delay device 6220 can be varied to change the optical delay to detect various depths in the target tissue 1001.

If the OCT system is a time domain system, the two subsystems use two different z-scanners because the two scanners operate in different ways. In this example, the z scanner of the surgical system operates by changing the divergence of the surgical beam in the beam conditioner unit without changing the path lengths of the beam in the surgical beam path. On the other hand, the time domain OCT scans the z-direction by physically changing the beam path by a variable delay or by moving the position of the reference beam return mirror. After calibration, the two z-scanners can be synchronized by the laser control module. The relationship between the two movements can be simplified to a linear or polynomial dependence, which the control module can handle or alternatively calibration points can define a look-up table to provide proper scaling. Spectral/Fourier domain and frequency swept source OCT devices have no z-scanner, the length of the reference arm is static. Besides reducing costs, cross calibration of the two systems will be relatively straightforward. There is no need to compensate for differences arising from image distortions in the focusing optics or from the differences of the scanners of the two systems since they are shared.

In practical implementations of the surgical systems, the focusing objective lens 5600 is slidably or movably mounted on a base and the weight of the objective lens is balanced to limit the force on the patient's eye. The patient interface 3300 can include an applanation lens attached to a patient interface mount. The patient interface mount is attached to a mounting unit, which holds the focusing objective lens. This mounting unit is designed to ensure a stable connection between the patient interface and the system in case of unavoidable movement of the patient and allows gentler docking of the patient interface onto the eye. Various implementations for the focusing objective lens can be used and one example is described in U.S. Pat. No. 5,336,215 to Hsueh. This presence of an adjustable focusing objective lens can change the optical path length of the optical probe light as part of the optical interferometer for the OCT sub-system. Movement of the objective lens 5600 and patient interface 3300 can change the path length differences between the reference beam and the imaging signal beam of the OCT in an uncontrolled way and this may degrade the OCT depth information detected by the OCT. This would happen not only in time-domain but also in spectral/Fourier domain and frequency-swept OCT systems.

FIGS. 13 and 14 show exemplary imaging-guided laser surgical systems that address the technical issue associated with the adjustable focusing objective lens.

The system in FIG. 13 provides a position sensing device 7110 coupled to the movable focusing objective lens 7100 to measure the position of the objective lens 7100 on a slide-

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able mount and communicates the measured position to a control module **7200** in the OCT system. The control system **6100** can control and move the position of the objective lens **7100** to adjust the optical path length traveled by the imaging signal beam for the OCT operation and the position of the lens **7100** is measured and monitored by the position encoder **7110** and direct fed to the OCT control **7200**. The control module **7200** in the OCT system applies an algorithm, when assembling a 3D image in processing the OCT data, to compensate for differences between the reference arm and the signal arm of the interferometer inside the OCT caused by the movement of the focusing objective lens **7100** relative to the patient interface **3300**. The proper amount of the change in the position of the lens **7100** computed by the OCT control module **7200** is sent to the control **6100** which controls the lens **7100** to change its position.

FIG. 14 shows another exemplary system where the return mirror **6230** in the reference arm of the interferometer of the OCT system or at least one part in an optical path length delay assembly of the OCT system is rigidly attached to the movable focusing objective lens **7100** so the signal arm and the reference arm undergo the same amount of change in the optical path length when the objective lens **7100** moves. As such, the movement of the objective lens **7100** on the slide is automatically compensated for path-length differences in the OCT system without additional need for a computational compensation.

The above examples for imaging-guided laser surgical systems, the laser surgical system and the OCT system use different light sources. In an even more complete integration between the laser surgical system and the OCT system, a femtosecond surgical laser as a light source for the surgical laser beam can also be used as the light source for the OCT system.

FIG. 15 shows an example where a femtosecond pulse laser in a light module **9100** is used to generate both the surgical laser beam for surgical operations and the probe light beam for OCT imaging. A beam splitter **9300** is provided to split the laser beam into a first beam as both the surgical laser beam and the signal beam for the OCT and a second beam as the reference beam for the OCT. The first beam is directed through an x-y scanner **6410** which scans the beam in the x and y directions perpendicular to the propagation direction of the first beam and a second scanner (z scanner) **6420** that changes the divergence of the beam to adjust the focusing of the first beam at the target tissue **1001**. This first beam performs the surgical operations at the target tissue **1001** and a portion of this first beam is back scattered to the patient interface and is collected by the objective lens as the signal beam for the signal arm of the optical interferometer of the OCT system. This returned light is combined with the second beam that is reflected by a return mirror **6230** in the reference arm and is delayed by an adjustable optical delay element **6220** for a time-domain OCT to control the path difference between the signal and reference beams in imaging different depths of the target tissue **1001**. The control system **9200** controls the system operations.

Surgical practice on the cornea has shown that a pulse duration of several hundred femtoseconds may be sufficient to achieve good surgical performance, while for OCT of a sufficient depth resolution broader spectral bandwidth generated by shorter pulses, e.g., below several tens of femtoseconds, are needed. In this context, the design of the OCT device dictates the duration of the pulses from the femtosecond surgical laser.

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FIG. 16 shows another imaging-guided system that uses a single pulsed laser **9100** to produce the surgical light and the imaging light. A nonlinear spectral broadening media **9400** is placed in the output optical path of the femtosecond pulsed laser to use an optical non-linear process such as white light generation or spectral broadening to broaden the spectral bandwidth of the pulses from a laser source of relatively longer pulses, several hundred femtoseconds normally used in surgery. The media **9400** can be a fiber-optic material, for example. The light intensity requirements of the two systems are different and a mechanism to adjust beam intensities can be implemented to meet such requirements in the two systems. For example, beam steering mirrors, beam shutters or attenuators can be provided in the optical paths of the two systems to properly control the presence and intensity of the beam when taking an OCT image or performing surgery in order to protect the patient and sensitive instruments from excessive light intensity.

In operation, the above examples in FIGS. 8/16 can be used to perform imaging-guided laser surgery. FIG. 17 shows one example of a method for performing laser surgery by using an imaging-guided laser surgical system. This method uses a patient interface in the system to engage to and to hold a target tissue under surgery in position and simultaneously directs a surgical laser beam of laser pulses from a laser in the system and an optical probe beam from the OCT module in the system to the patient interface into the target tissue. The surgical laser beam is controlled to perform laser surgery in the target tissue and the OCT module is operated to obtain OCT images inside the target tissue from light of the optical probe beam returning from the target tissue. The position information in the obtained OCT images is applied in focusing and scanning of the surgical laser beam to adjust the focusing and scanning of the surgical laser beam in the target tissue before or during surgery.

FIG. 18 shows an example of an OCT image of an eye. The contacting surface of the applanation lens in the patent interface can be configured to have a curvature that minimizes distortions or folds in the cornea due to the pressure exerted on the eye during applanation. After the eye is successfully applanated at the patient interface, an OCT image can be obtained. As illustrated in FIG. 18, the curvature of the lens and cornea as well as the distances between the lens and cornea are identifiable in the OCT image. Subtler features such as the epithelium-cornea interface are detectable. Each of these identifiable features may be used as an internal reference of the laser coordinates with the eye. The coordinates of the cornea and lens can be digitized using well-established computer vision algorithms such as Edge or Blob detection. Once the coordinates of the lens are established, they can be used to control the focusing and positioning of the surgical laser beam for the surgery.

Alternatively, a calibration sample material may be used to form a 3-D array of reference marks at locations with known position coordinates. The OCT image of the calibration sample material can be obtained to establish a mapping relationship between the known position coordinates of the reference marks and the OCT images of the reference marks in the obtained OCT image. This mapping relationship is stored as digital calibration data and is applied in controlling the focusing and scanning of the surgical laser beam during the surgery in the target tissue based on the OCT images of the target tissue obtained during the surgery. The OCT imaging system is used here as an example and this calibration can be applied to images obtained via other imaging techniques.

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In an imaging-guided laser surgical system described here, the surgical laser can produce relatively high peak powers sufficient to drive strong field/multi-photon ionization inside of the eye (i.e. inside of the cornea and lens) under high numerical aperture focusing. Under these conditions, one pulse from the surgical laser generates a plasma within the focal volume. Cooling of the plasma results in a well defined damage zone or “bubble” that may be used as a reference point. The following sections describe a calibration procedure for calibrating the surgical laser against an OCT-based imaging system using the damage zones created by the surgical laser.

Before surgery can be performed, the OCT is calibrated against the surgical laser to establish a relative positioning relationship so that the surgical laser can be controlled in position at the target tissue with respect to the position associated with images in the OCT image of the target tissue obtained by the OCT. One way for performing this calibration uses a pre-calibrated target or “phantom” which can be damaged by the laser as well as imaged with the OCT. The phantom can be fabricated from various materials such as a glass or hard plastic (e.g. PMMA) such that the material can permanently record optical damage created by the surgical laser. The phantom can also be selected to have optical or other properties (such as water content) that are similar to the surgical target.

The phantom can be, e.g., a cylindrical material having a diameter of at least 10 mm (or that of the scanning range of the delivery system) and a cylindrical length of at least 10 mm long spanning the distance of the epithelium to the crystalline lens of the eye, or as long as the scanning depth of the surgical system. The upper surface of the phantom can be curved to mate seamlessly with the patient interface or the phantom material may be compressible to allow full appplanation. The phantom may have a three dimensional grid such that both the laser position (in x and y) and focus (z), as well as the OCT image can be referenced against the phantom.

FIGS. 19A-19D illustrate two exemplary configurations for the phantom. FIG. 19A illustrates a phantom that is segmented into thin disks. FIG. 19B shows a single disk patterned to have a grid of reference marks as a reference for determining the laser position across the phantom (i.e. the x- and y-coordinates). The z-coordinate (depth) can be determined by removing an individual disk from the stack and imaging it under a confocal microscope.

FIG. 19C illustrates a phantom that can be separated into two halves. Similar to the segmented phantom in FIG. 19A, this phantom is structured to contain a grid of reference marks as a reference for determining the laser position in the x- and y-coordinates. Depth information can be extracted by separating the phantom into the two halves and measuring the distance between damage zones. The combined information can provide the parameters for image guided surgery.

FIG. 20 shows a surgical system part of the imaging-guided laser surgical system. This system includes steering mirrors which may be actuated by actuators such as galvanometers or voice coils, an objective lens e and a disposable patient interface. The surgical laser beam is reflected from the steering mirrors through the objective lens. The objective lens focuses the beam just after the patient interface. Scanning in the x- and y-coordinates is performed by changing the angle of the beam relative to the objective lens. Scanning in z-plane is accomplished by changing the divergence of the incoming beam using a system of lens upstream to the steering mirrors.

In this example, the conical section of the disposable patient interface may be either air spaced or solid and the

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section interfacing with the patient includes a curved contact lens. The curved contact lens can be fabricated from fused silica or other material resistant to forming color centers when irradiated with ionizing radiation. The radius of curvature is on the upper limit of what is compatible with the eye, e.g., about 10 mm.

The first step in the calibration procedure is docking the patient interface with the phantom. The curvature of the phantom matches the curvature of the patient interface. After 10 docking, the next step in the procedure involves creating optical damage inside of the phantom to produce the reference marks.

FIG. 21 shows examples of actual damage zones produced by a femtosecond laser in glass. The separation between the damage zones is on average 8 μm (the pulse energy is 2.2 μJ with duration of 580 fs at full width at half maximum). The optical damage depicted in FIG. 21 shows that the damage zones created by the femtosecond laser are well-defined and discrete. In the example shown, the damage zones have a diameter of about 2.5 μm . Optical damage zones similar to that shown in FIG. 20 are created in the phantom at various depths to form a 3-D array of the reference marks. These damage zones are referenced against the calibrated phantom either by extracting the appropriate disks and imaging it under a confocal microscope (FIG. 19A) or by splitting the phantom into two halves and measuring the depth using a micrometer (FIG. 19C). The x- and y-coordinates can be established from the pre-calibrated grid.

After damaging the phantom with the surgical laser, OCT on the phantom is performed. The OCT imaging system provides a 3D rendering of the phantom establishing a relationship between the OCT coordinate system and the phantom. The damage zones are detectable with the imaging system. The OCT and laser may be cross-calibrated using the phantom’s internal standard. After the OCT and the laser are referenced against each other, the phantom can be discarded.

Prior to surgery, the calibration can be verified. This 40 verification step involves creating optical damage at various positions inside of a second phantom. The optical damage should be intense enough such that the multiple damage zones which create a circular pattern can be imaged by the OCT. After the pattern is created, the second phantom is 45 imaged with the OCT. Comparison of the OCT image with the laser coordinates provides the final check of the system calibration prior to surgery.

Once the coordinates are fed into the laser, laser surgery can be performed inside the eye. This involves photocoagulation of the lens using the laser, as well as other laser treatments to the eye. The surgery can be stopped at any time and the anterior segment of the eye (FIG. 17) can be re-imaged to monitor the progress of the surgery; moreover, after the IOL is inserted, imaging the IOL (with light 50 or no appplanation) provides information regarding the position of the IOL in the eye. This information may be utilized by the physician to refine the position of the IOL.

FIG. 22 shows an example of the calibration process and the post-calibration surgical operation. This example illustrates a method for performing laser surgery by using an 60 imaging-guided laser surgical system. This system can include using a patient interface in the system, that is engaged to hold a target tissue under surgery in position, to hold a calibration sample material during a calibration process before performing a surgery; directing a surgical laser beam of laser pulses 65 from a laser in the system to the patient interface into the calibration sample material to burn reference marks at

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selected three-dimensional reference locations; directing an optical probe beam from an optical coherence tomography (OCT) module in the system to the patient interface into the calibration sample material to capture OCT images of the burnt reference marks; and establishing a relationship between positioning coordinates of the OCT module and the burnt reference marks. After the establishing the relationship, a patient interface in the system is used to engage to and to hold a target tissue under surgery in position. The surgical laser beam of laser pulses and the optical probe beam are directed to the patient interface into the target tissue. The surgical laser beam is controlled to perform laser surgery in the target tissue. The OCT module is operated to obtain OCT images inside the target tissue from light of the optical probe beam returning from the target tissue and the position information in the obtained OCT images and the established relationship are applied in focusing and scanning of the surgical laser beam to adjust the focusing and scanning of the surgical laser beam in the target tissue during surgery. While such calibrations can be performed immediately prior to laser surgery, they can also be performed at various intervals before a procedure, using calibration validations that demonstrated a lack of drift or change in calibration during such intervals.

The following examples describe imaging-guided laser surgical techniques and systems that use images of laser-induced photodisruption byproducts for alignment of the surgical laser beam.

FIGS. 23A and 23B illustrate another implementation of the present technique in which actual photodisruption byproducts in the target tissue are used to guide further laser placement. A pulsed laser 1710, such as a femtosecond or picosecond laser, is used to produce a laser beam 1712 with laser pulses to cause photodisruption in a target tissue 1001. The target tissue 1001 may be a part of a body part 1700 of a subject, e.g., a portion of the lens of one eye. The laser beam 1712 is focused and directed by an optics module for the laser 1710 to a target tissue position in the target tissue 1001 to achieve a certain surgical effect. The target surface is optically coupled to the laser optics module by an application plate 1730 that transmits the laser wavelength, as well as image wavelengths from the target tissue. The application plate 1730 can be an application lens. An imaging device 1720 is provided to collect reflected or scattered light or sound from the target tissue 1001 to capture images of the target tissue 1001 either before or after (or both) the application plate is applied. The captured imaging data is then processed by the laser system control module to determine the desired target tissue position. The laser system control module moves or adjusts optical or laser elements based on standard optical models to ensure that the center of photodisruption byproduct 1702 overlaps with the target tissue position. This can be a dynamic alignment process where the images of the photodisruption byproduct 1702 and the target tissue 1001 are continuously monitored during the surgical process to ensure that the laser beam is properly positioned at each target tissue position.

In one implementation, the laser system can be operated in two modes: first in a diagnostic mode in which the laser beam 1712 is initially aligned by using alignment laser pulses to create photodisruption byproduct 1702 for alignment and then in a surgical mode where surgical laser pulses are generated to perform the actual surgical operation. In both modes, the images of the disruption byproduct 1702 and the target tissue 1001 are monitored to control the beam alignment. FIG. 17A shows the diagnostic mode where the alignment laser pulses in the laser beam 1712 may be set at

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a different energy level than the energy level of the surgical laser pulses. For example, the alignment laser pulses may be less energetic than the surgical laser pulses but sufficient to cause significant photodisruption in the tissue to capture the photodisruption byproduct 1702 at the imaging device 1720. The resolution of this coarse targeting may not be sufficient to provide desired surgical effect. Based on the captured images, the laser beam 1712 can be aligned properly. After this initial alignment, the laser 1710 can be controlled to produce the surgical laser pulses at a higher energy level to perform the surgery. Because the surgical laser pulses are at a different energy level than the alignment laser pulses, the nonlinear effects in the tissue material in the photodisruption can cause the laser beam 1712 to be focused at a different position from the beam position during the diagnostic mode. Therefore, the alignment achieved during the diagnostic mode is a coarse alignment and additional alignment can be further performed to precisely position each surgical laser pulse during the surgical mode when the surgical laser pulses perform the actual surgery. Referring to FIG. 23A, the imaging device 1720 captures the images from the target tissue 1001 during the surgical mode and the laser control module adjust the laser beam 1712 to place the focus position 1714 of the laser beam 1712 onto the desired target tissue position in the target tissue 1001. This process is performed for each target tissue position.

FIG. 24 shows one implementation of the laser alignment where the laser beam is first approximately aimed at the target tissue and then the image of the photodisruption byproduct is captured and used to align the laser beam. The image of the target tissue of the body part as the target tissue and the image of a reference on the body part are monitored to aim the pulsed laser beam at the target tissue. The images of photodisruption byproduct and the target tissue are used to adjust the pulsed laser beam to overlap the location of the photodisruption byproduct with the target tissue.

FIG. 25 shows one implementation of the laser alignment method based on imaging photodisruption byproduct in the target tissue in laser surgery. In this method, a pulsed laser beam is aimed at a target tissue location within target tissue 40 to deliver a sequence of initial alignment laser pulses to the target tissue location. The images of the target tissue location and photodisruption byproduct caused by the initial alignment laser pulses are monitored to obtain a location of the photodisruption byproduct relative to the target tissue location. The location of photodisruption byproduct caused by surgical laser pulses at a surgical pulse energy level different from the initial alignment laser pulses is determined when the pulsed laser beam of the surgical laser pulses is placed 45 at the target tissue location. The pulsed laser beam is controlled to carry surgical laser pulses at the surgical pulse energy level. The position of the pulsed laser beam is adjusted at the surgical pulse energy level to place the location of photodisruption byproduct at the determined location. While monitoring images of the target tissue and the photodisruption byproduct, the position of the pulsed laser beam at the surgical pulse energy level is adjusted to place the location of photodisruption byproduct at a respective determined location when moving the pulsed laser beam 50 to a new target tissue location within the target tissue.

FIG. 26 shows an exemplary laser surgical system based on the laser alignment using the image of the photodisruption byproduct. An optics module 2010 is provided to focus and direct the laser beam to the target tissue 1700. The optics module 2010 can include one or more lenses and may further include one or more reflectors. A control actuator is included 55 in the optics module 2010 to adjust the focusing and the

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beam direction in response to a beam control signal. A system control module 2020 is provided to control both the pulsed laser 1010 via a laser control signal and the optics module 2010 via the beam control signal. The system control module 2020 processes image data from the imaging device 2030 that includes the position offset information for the photodisruption byproduct 1702 from the target tissue position in the target tissue 1700. Based on the information obtained from the image, the beam control signal is generated to control the optics module 2010 which adjusts the laser beam. A digital processing unit is included in the system control module 2020 to perform various data processing for the laser alignment.

The imaging device 2030 can be implemented in various forms, including an optical coherent tomography (OCT) device. In addition, an ultrasound imaging device can also be used. The position of the laser focus is moved so as to place it grossly located at the target at the resolution of the imaging device. The error in the referencing of the laser focus to the target and possible non-linear optical effects such as self focusing that make it difficult to accurately predict the location of the laser focus and subsequent photodisruption event. Various calibration methods, including the use of a model system or software program to predict focusing of the laser inside a material can be used to get a coarse targeting of the laser within the imaged tissue. The imaging of the target can be performed both before and after the photodisruption. The position of the photodisruption byproducts relative to the target is used to shift the focal point of the laser to better localize the laser focus and photodisruption process at or relative to the target. Thus the actual photodisruption event is used to provide a precise targeting for the placement of subsequent surgical pulses.

Photodisruption for targeting during the diagnostic mode can be performed at a lower, higher or the same energy level that is required for the later surgical processing in the surgical mode of the system. A calibration may be used to correlate the localization of the photodisruptive event performed at a different energy in diagnostic mode with the predicted localization at the surgical energy because the optical pulse energy level can affect the exact location of the photodisruptive event. Once this initial localization and alignment is performed, a volume or pattern of laser pulses (or a single pulse) can be delivered relative to this positioning. Additional sampling images can be made during the course of delivering the additional laser pulses to ensure proper localization of the laser (the sampling images may be obtained with use of lower, higher or the same energy pulses). In one implementation, an ultrasound device is used to detect the cavitation bubble or shock wave or other photodisruption byproduct. The localization of this can then be correlated with imaging of the target, obtained via ultrasound or other modality. In another embodiment, the imaging device is simply a biomicroscope or other optical visualization of the photodisruption event by the operator, such as optical coherence tomography. With the initial observation, the laser focus is moved to the desired target position, after which a pattern or volume of pulses is delivered relative to this initial position.

As a specific example, a laser system for precise subsurface photodisruption can include means for generating laser pulses capable of generating photodisruption at repetition rates of 100-1000 Million pulses per second, means for coarsely focusing laser pulses to a target below a surface using an image of the target and a calibration of the laser focus to that image without creating a surgical effect, means for detecting or visualizing below a surface to provide an

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image or visualization of a target the adjacent space or material around the target and the byproducts of at least one photodisruptive event coarsely localized near the target, means for correlating the position of the byproducts of photodisruption with that of the sub surface target at least once and moving the focus of the laser pulse to position the byproducts of photodisruption at the sub surface target or at a relative position relative to the target, means for delivering a subsequent train of at least one additional laser pulse in pattern relative to the position indicated by the above fine correlation of the byproducts of photodisruption with that of the sub surface target, and means for continuing to monitor the photodisruptive events during placement of the subsequent train of pulses to further fine tune the position of the subsequent laser pulses relative to the same or revised target being imaged.

The above techniques and systems can be used deliver high repetition rate laser pulses to subsurface targets with a precision required for contiguous pulse placement, as needed for cutting or volume disruption applications. This can be accomplished with or without the use of a reference source on the surface of the target and can take into account movement of the target following applanation or during placement of laser pulses.

While this specification described various embodiments and implementations, these should not be construed as limitations on the scope of an invention or of what may be claimed, but rather as descriptions of features specific to particular embodiments of the invention. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or a variation of a sub-combination. Also, enhancements, combinations, extensions and variations can be made based on what is disclosed and illustrated.

What is claimed is:

1. A method of treating a crystalline lens of an eye with a laser, the method comprising:
 - selecting a surgical region of the lens; and
 - forming an incision in the surgical region on a layer-by-layer basis by scanning a laser beam with an XY scanner of a laser delivery optics along a curved focal plane of the laser delivery optics to form a line of bubbles in each layer without adjusting a Z scanner of the laser delivery optics at a scanning rate of the XY scanner, wherein:
 - an orientation of a portion of the incisions is one of an orientation intersecting fibers of the lens and an orientation non-transverse to an axis of the eye; and
 - the incision has a spatial extent in a Z direction in the range of 0.5-10 mm, and in an X-Y plane in the range of 2-10 mm.
2. The method of claim 1, wherein the non-transverse orientation of the incision is one of:
 - an orientation substantially parallel to the axis of the eye; and
 - an orientation making a less than 90 degree angle with the axis of the eye.

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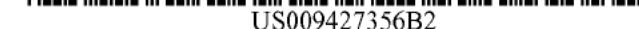
3. The method of claim 1, wherein:
a spatial extent of the incision along the axis of the eye is longer than the spatial extent transverse to the axis of the eye.
4. The method of claim 1, wherein:
the axis of the eye is one of a visual axis, an optic axis, a line of sight and a pupillary axis.
5. The method of claim 1, wherein:
the incision cuts the fibers into parts approximately at the intersection of the incision and the fibers; and
the modified property of the lens is a weakening of a biomechanical property of the lens.
6. The method of claim 1, wherein:
the incision cuts the fibers at or near sutures of the fibers.
7. The method of claim 1, wherein:
the incision avoids cutting sutures in the lens.
8. The method of claim 1, wherein the applying laser pulses comprises:
applying the laser pulses to generate gas bubbles which form the incision,
wherein an orientation of the incision is aligned with a preferential direction of expansion of the generated gas bubbles.
9. The method of claim 1, wherein the applying the laser pulses comprises:
moving the focal point of the applied laser beam along a posterior to anterior direction within the lens.
10. The method of claim 1, wherein:
the method comprises forming no more than one incision;
and
the laser pulses are applied in a continuous manner to form the incision without repositioning the laser or interrupting the application of the laser.
11. The method of claim 1, wherein the incision has a form aligned with the axis of the eye, the form being of at least one of:
a cylinder, a set of concentric cylinders, a set of cylinders connected by one or more connecting line, a curved surface, a cone, a spiral, a layered spiral with smooth lines connecting layers of the spiral and a tilted cylinder.
12. The method of claim 1, wherein the incision has a form aligned with the axis of the eye, the form being at least one of:
a plane, two or more crossing planes, a combination of planes and connecting arcs, and a combination of planes and cylinders.
13. The method of claim 1, wherein the applying the laser pulses comprises:
applying the laser pulses to form a first ring with a first radius in a posterior layer of the lens;
applying the laser pulses to form a connector line between the first and a second ring in the posterior layer;
applying the laser pulses to form the second ring with a second radius in the posterior layer; and
repeating multiple times the formation of the first ring, the second ring and the connector line in layers sequentially anterior to the posterior layer,
wherein the first rings in the sequential layers form a first cylinder, the second rings form a second cylinder, the cylinders being connected by the connector lines.
14. The method of claim 13, wherein:
the connector lines in sequential layers are one of:
aligned to form connector planes; and
not-aligned from layer to layer.

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15. The method of claim 1, comprising:
forming a posterior spiral in a posterior layer;
forming a smooth connector line starting near an end of the posterior spiral in the posterior layer, the connector line smoothly bending and rising to a central region of a layer anterior to the posterior layer; and
forming an anterior spiral starting at the end of the smooth connector line in the central region of the anterior layer.
16. The method of claim 15, wherein the posterior spiral and the anterior spiral are essentially aligned to form a spiral with an extent in the Z direction.
17. The method of claim 1, wherein the applying the laser pulses comprises:
selecting laser-parameters sufficient to create bubbles in the lens, but insufficient to cause harm to a retina of the eye.
18. The method of claim 1, wherein the applying the laser pulses comprises:
applying the laser pulses with laser-parameters insufficient to fragment the lens to a degree suitable for removal, if the incision were transverse to the axis of the eye.
19. The method of claim 18, wherein the laser-parameters comprise:
a laser pulse energy in the range of 0.5 microJ to 50 microJ;
a duration of a laser pulse in the range of 0.005 picoseconds to 25 picoseconds;
a repetition rate of applying laser pulses in the range of 1 kHz to 10 MHz; and
a separation distance of target regions of laser pulses in the range of 1 micron to 100 microns.
20. The method of claim 1, wherein the applying the laser pulses comprises:
applying the laser pulses with varying energy as the incision is formed.
21. The method of claim 20, wherein the energy is varied during at least one of:
a Z directional scanning; and
an X-Y directional scanning.
22. The method of claim 20, wherein the energy is varied in relation to a measurement of an optical property of an eye tissue.
23. The method of claim 1, comprising:
forming the incision on a layer-by-layer basis, wherein one or more layers are at least partially formed along a curved focal plane of a laser delivery system.
24. The method of claim 1, comprising:
a Z directional scanner is adjusted at a slower rate than an X-Y directional scanner when forming a layer of one or more incisions.
25. The method of claim 1, further comprising:
forming a protection layer in a posterior portion of the lens, positioned to block a large portion of the laser pulses applied to form the incision.
26. The method of claim 1, wherein the incision fragments at least a portion of the lens, the method further comprising:
removing the fragmented portion of the lens.
27. The method of claim 26, wherein the applying the laser pulses comprises:
applying laser pulses with laser parameters which do not cause lasting damage to a retina of the eye, wherein the laser pulses fragment the lens to a degree suitable for removal; and
the time of the fragmentation is less than a minute.

* * * * *

EXHIBIT 6



US009427356B2

(12) **United States Patent**
Raksi(10) **Patent No.:** US 9,427,356 B2
(45) **Date of Patent:** *Aug. 30, 2016(54) **PHOTODISRUPTIVE LASER
FRAGMENTATION OF TISSUE**(71) Applicant: **Alcon LenSx, Inc.**, Aliso Viejo, CA (US)(72) Inventor: **Ferenc Raksi**, Mission Viejo, CA (US)(73) Assignee: **ALCON LENSX, INC.**, Aliso Viejo, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 64 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/451,881**(22) Filed: **Aug. 5, 2014**(65) **Prior Publication Data**

US 2014/0350531 A1 Nov. 27, 2014

Related U.S. Application Data

(63) Continuation of application No. 12/351,784, filed on Jan. 9, 2009, now abandoned.

(60) Provisional application No. 61/020,115, filed on Jan. 9, 2008.

(51) **Int. Cl.***A61F 9/008* (2006.01)*A61F 9/007* (2006.01)(52) **U.S. Cl.**CPC *A61F 9/00825* (2013.01); *A61F 9/008* (2013.01); *A61F 9/00736* (2013.01); *A61F 2009/0087* (2013.01); *A61F 2009/00844* (2013.01); *A61F 2009/00897* (2013.01)(58) **Field of Classification Search**CPC *A61F 9/00825*; *A61F 9/00736*; *A61F 9/008*; *A61F 2009/0087*; *A61F 2009/00844*USPC 606/4-6, 10, 11
See application file for complete search history.(56) **References Cited**

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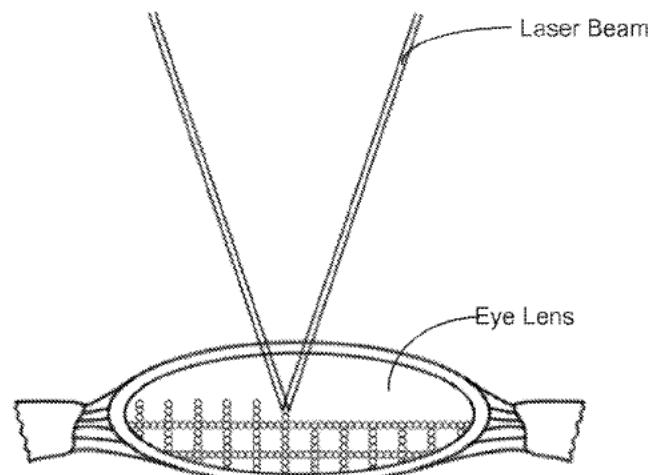
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Primary Examiner — Ryan J Severson*Assistant Examiner* — Anh Dang(74) *Attorney, Agent, or Firm* — S. Brannon Latimer(57) **ABSTRACT**

A method of photodisruptive laser surgery includes selecting a target region of a tissue for fragmentation, directing a beam of laser pulses to the selected target region of the tissue, and forming cells in the target region of the tissue by directing the laser beam to generate cell boundaries. The cells can be arranged in regular or irregular arrays. The cells can be generated in parallel or successively, with cell sizes and laser parameters which reduce the time of ophthalmic surgery considerably.

14 Claims, 8 Drawing Sheets

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FIG. 1a

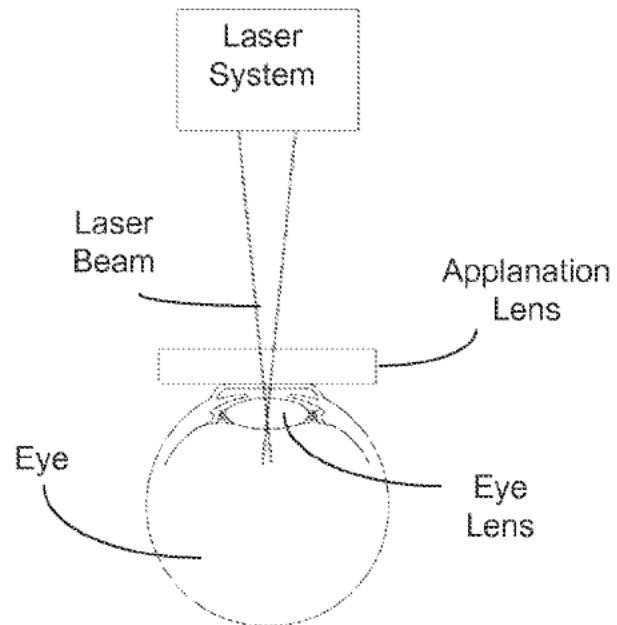
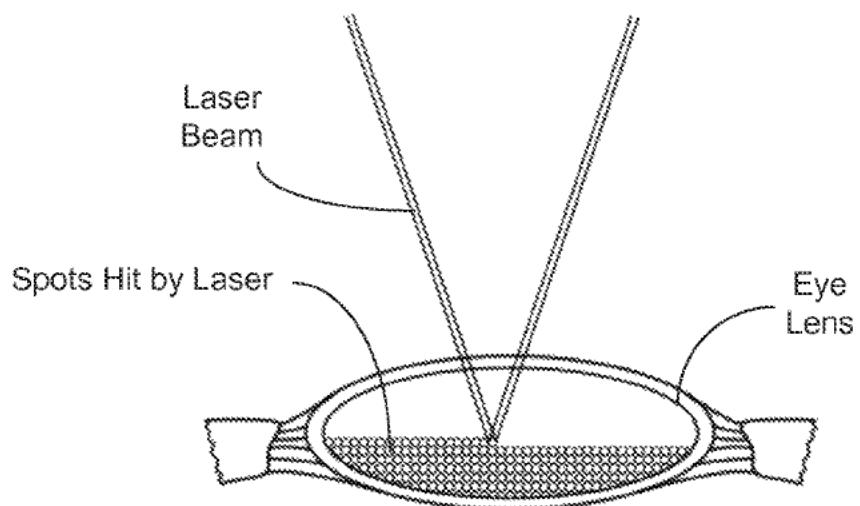


FIG. 1b



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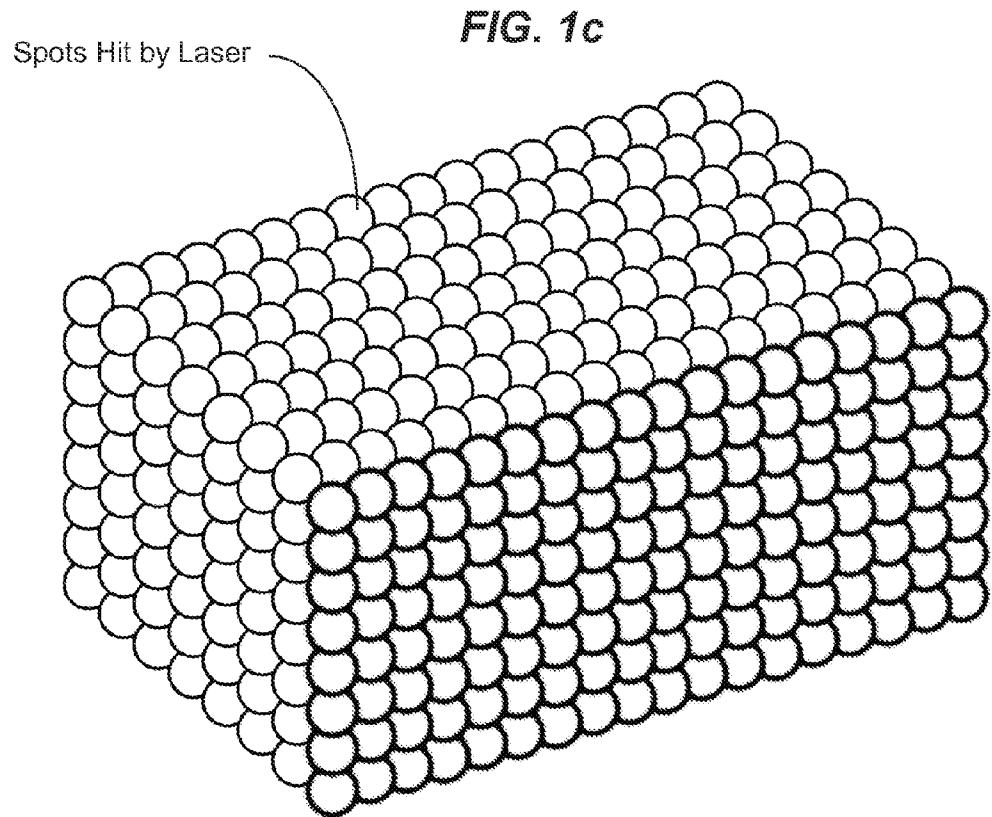
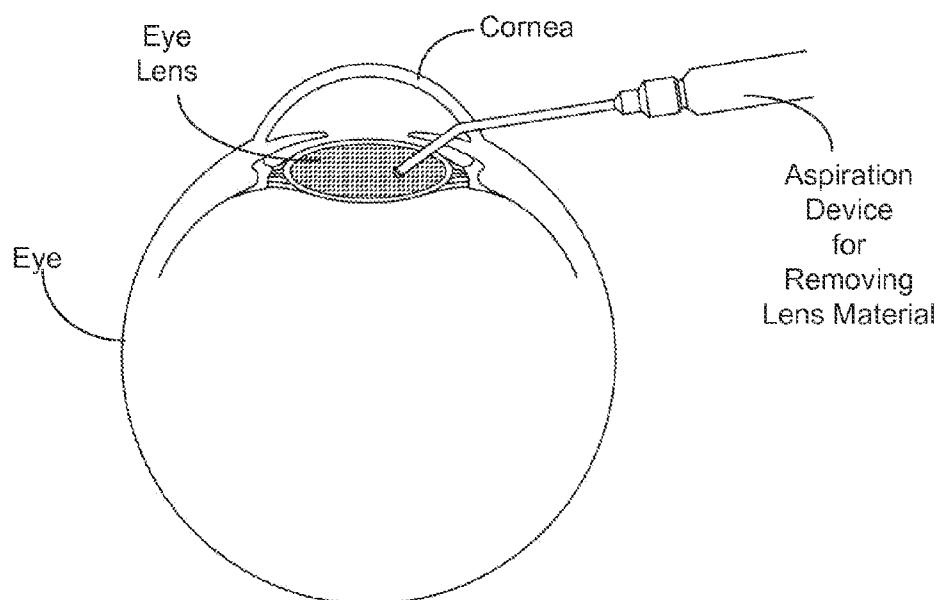


FIG. 2



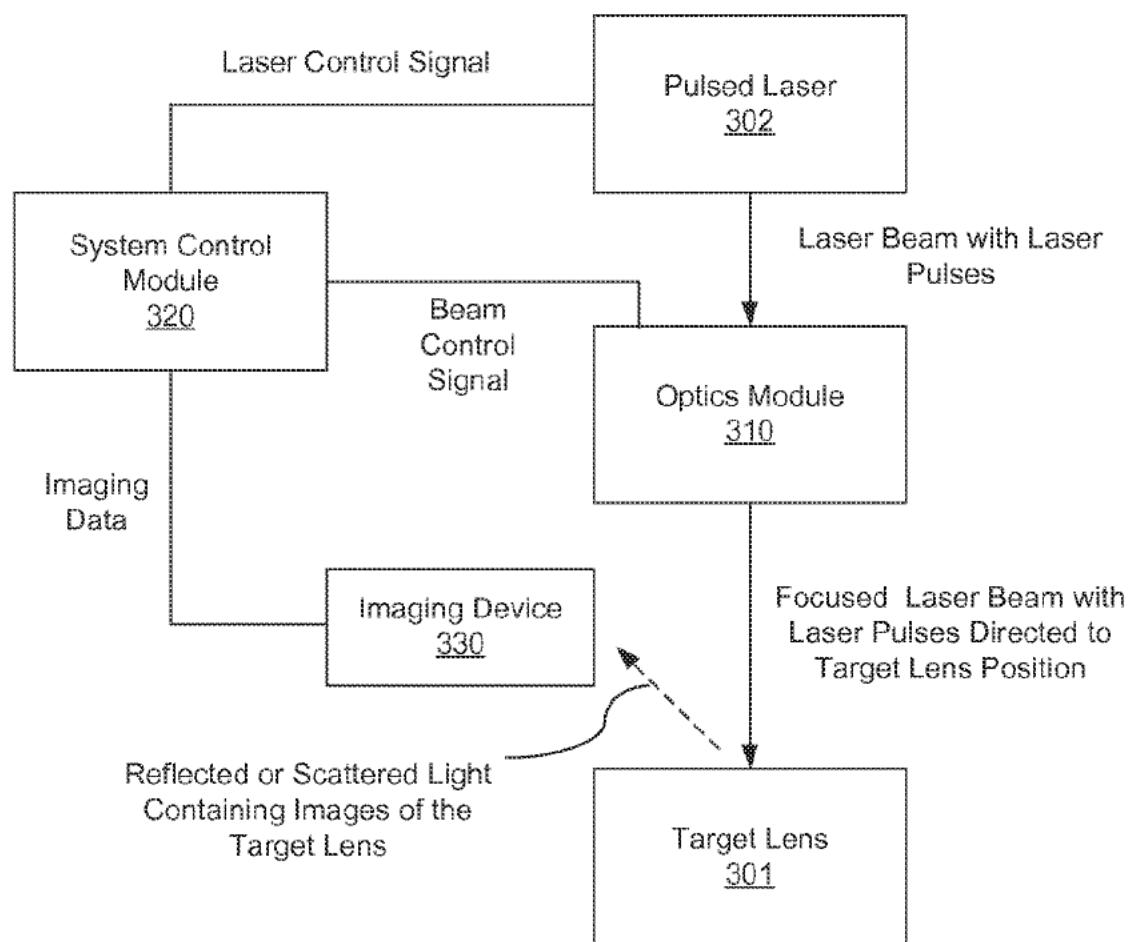
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FIG. 3



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FIG. 4a

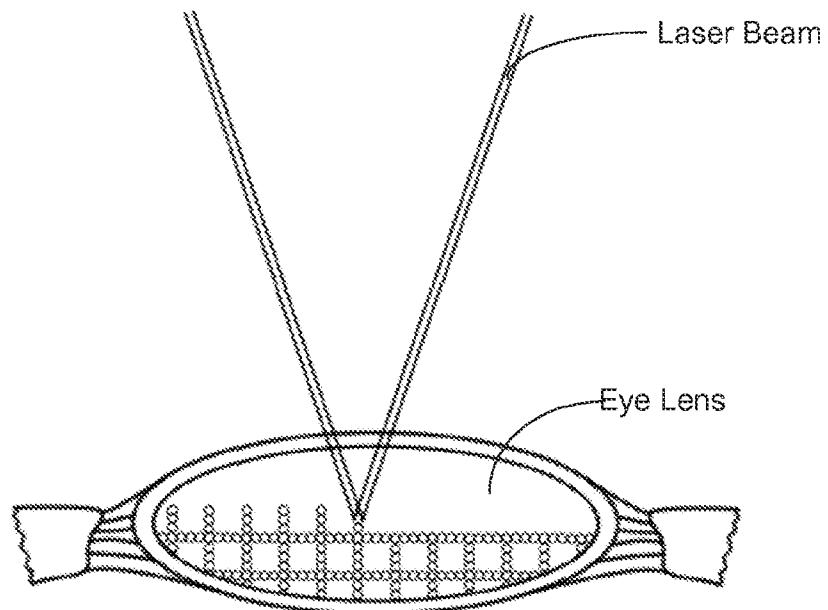
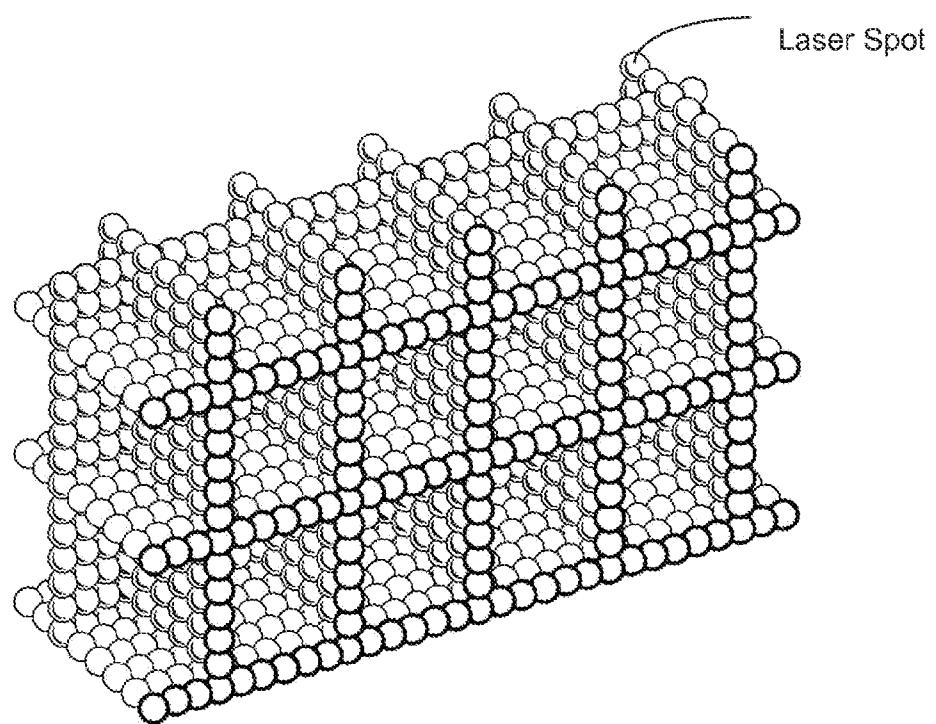


FIG. 4b



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FIG. 5a

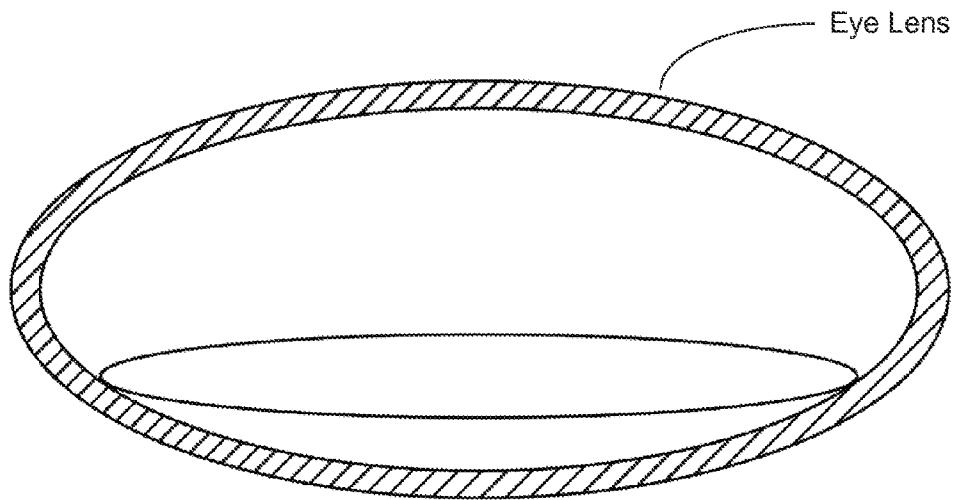
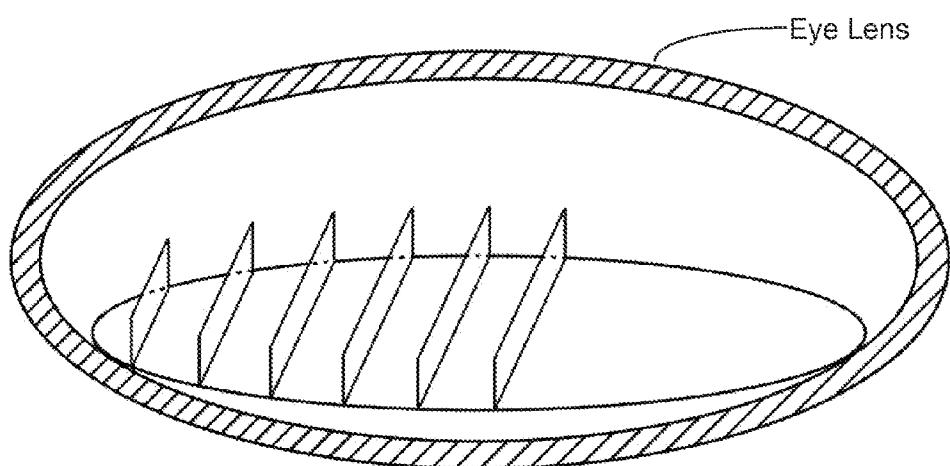


FIG. 5b



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FIG. 5c

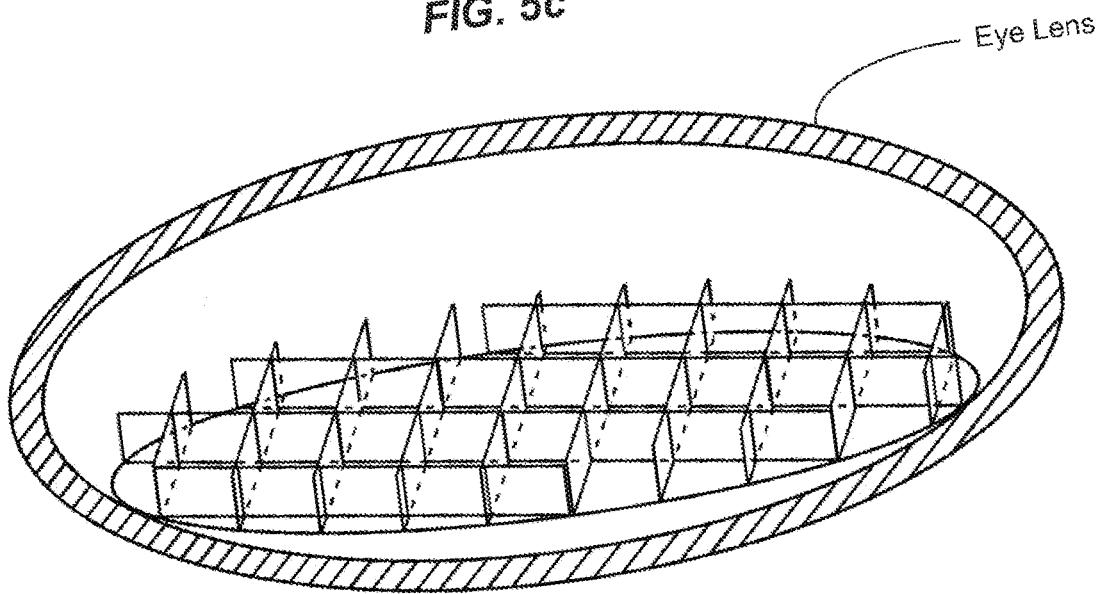
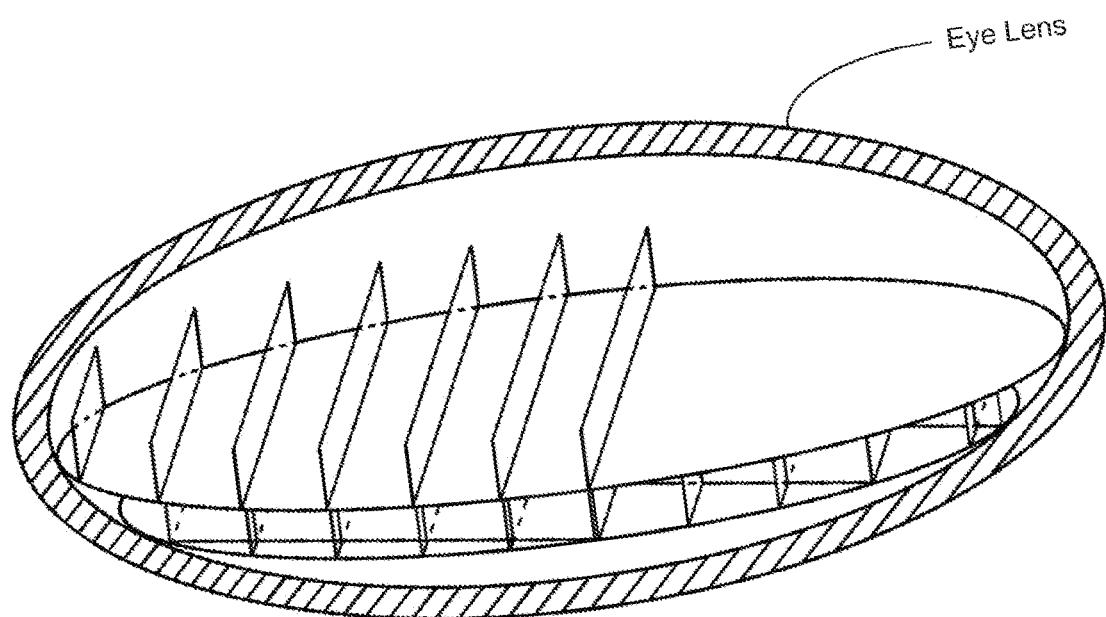


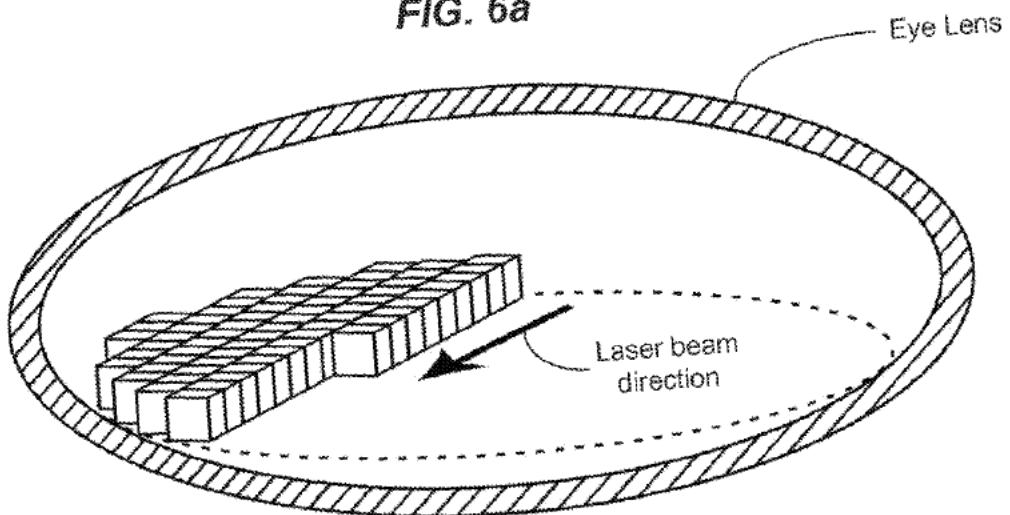
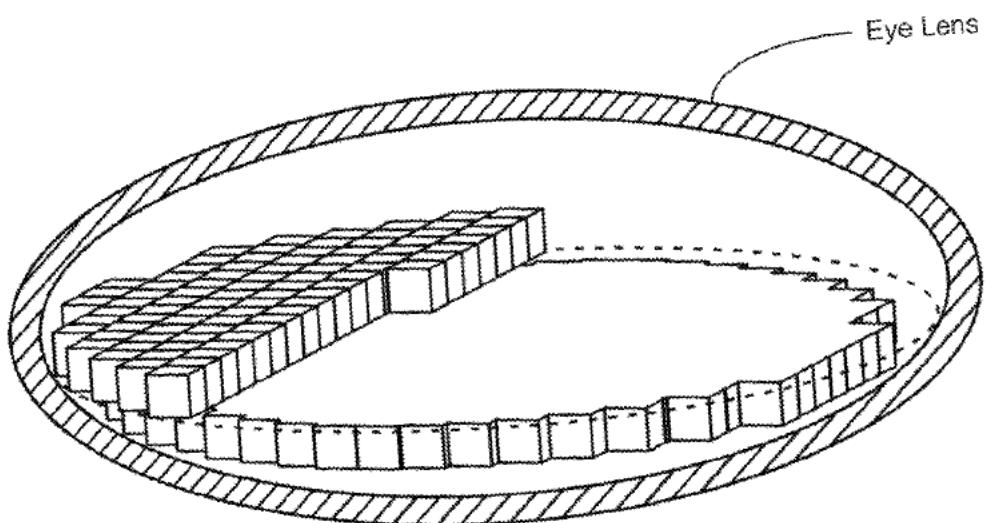
FIG. 5d



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US 9,427,356 B2**FIG. 6a****FIG. 6b**

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FIG. 7a

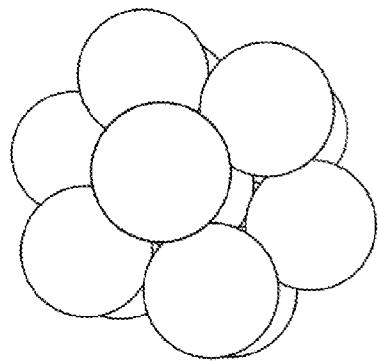


FIG. 7b

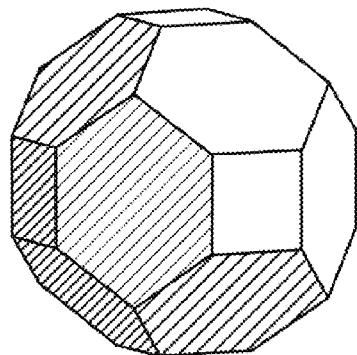
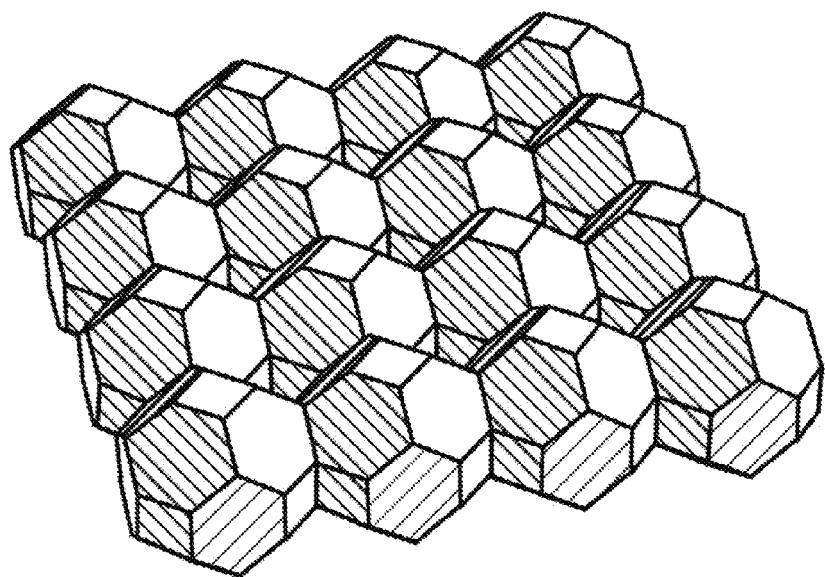


FIG. 7c



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**PHOTODISRUPTIVE LASER
FRAGMENTATION OF TISSUE**

CROSS REFERENCE TO RELATED
APPLICATION

This application is a continuation of, and thus claims benefit of and priority from U.S. patent application "Photodisruptive laser fragmentation of tissue", Ser. No. 12/351,784, filed on Jan. 9, 2009, that claims benefit of and priority from provisional application "Photodisruptive laser fragmentation of tissue", Ser. No. 61/020,115, filed on Jan. 9, 2008, both applications hereby incorporated in their entirety by reference.

BACKGROUND

This application relates to laser surgery techniques and systems for operating on eyes.

Laser light can be used to perform surgical operations on various parts of an eye for vision correction and other medical treatment. Techniques for performing such procedures with higher efficiency may provide desired benefits.

SUMMARY

A method of photodisruptive laser surgery and corresponding system are provided. In some implementations the method of fragmenting biological tissue with a photodisruptive laser includes selecting a target region of the tissue for fragmentation, directing a beam of laser pulses to the selected target region of the tissue, and forming cells in the target region of the tissue by directing the laser beam to generate cell boundaries.

In some implementations the tissue is a tissue of an eye.

In some implementations the tissue is a crystalline lens of the eye.

In some implementations the method further includes inserting an aspiration needle into the target region and removing fragmented tissue from the target region already scanned by the laser beam by using the aspiration needle.

In some implementations the forming the cells includes forming cells with size sufficiently small to pass through the aspiration needle.

In some implementations the forming the cells includes forming the cells arranged in an array.

In some implementations the array is a regular array.

In some implementations the regular array is one of a simple cubic lattice, a face centered lattice, a body centered lattice, a hexagonal lattice, a Bravais lattice, and a stack of two dimensional lattices.

In some implementations the array is essentially a random array.

In some implementations the forming the cells includes fragmenting the target tissue into cells of spheres or polyhedra.

In some implementations the forming the cells includes scanning the laser beam to form multiple cells in parallel in a layer.

In some implementations the forming the cells includes directing the laser beam to form individual cells successively.

In some implementations the forming the cells includes scanning the laser beam to form a cell array progressing from a posterior to an anterior direction, or scanning the laser beam to form a cell array progressing from an anterior to a posterior direction.

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In some implementations the directing the laser beam to generate cell boundaries includes generating the cell boundaries by creating layers of bubbles in the target region of the tissue.

5 In some implementations the creating layers of bubbles includes creating a layer of bubbles by applying a laser beam with an essentially constant power, or with a varying power.

In some implementations the directing the beam of laser pulses includes applying the laser pulses with a laser parameter of at least one of: a pulse duration between 0.01 picosecond and 50 picoseconds, a repetition rate between 10 kiloHertz and 100 megaHertz, a pulse energy between 1 microJoule and 25 microJoule, and a pulse target separation between 0.1 micron and 50 microns.

10 15 In some implementations the directing the beam of laser pulses comprises applying the laser pulses with a laser parameter based on a preoperative measurement of structural properties of the target region of the tissue, or an age dependent algorithm.

20 In some implementations the method also includes applying additional laser pulses to one or more locations outside the target region of the tissue to create an opening for an additional procedure.

25 In some implementations the method includes identifying a surgical goal, and selecting laser parameters and method features to achieve the identified surgical goal.

In some implementations the surgical goal is an optimization of one or more of a speed of the method of fragmenting, a total amount of energy applied to the eye during the fragmenting, and a total number of generated bubbles.

30 35 In some implementation the surgical goal is one or more of: maximization of the speed of the method of fragmenting, minimization of the total amount of energy applied to the eye during the fragmenting, and minimization of the total number of generated bubbles.

In some implementations the method includes selecting laser parameters and method features to achieve a total time of fragmentation of one of less than 2 minutes, less than 1 minute, and less than 30 seconds.

40 In some implementations the method includes selecting laser parameters and method features to achieve a ratio of a cell size to a bubble size of one of: larger than 10, larger than 100, and larger than 1000.

In some implementations a laser system for fragmenting biological tissue includes a pulsed laser to produce a laser beam of pulses, and a laser control module to direct the laser beam to a selected target region of the tissue and to direct the laser beam to generate cell boundaries to form cells in the target region of the tissue.

45 In some implementations the laser control module is configured to form cells in a regular array.

In some implementations the laser control module formed to generate the laser pulses with laser parameters of at least one of: a pulse duration between 0.01 and 50 picoseconds, a repetition rate between 10 kHz and 100 megahertz, a pulse energy between 1 microJoule and 25 microJoule, and a pulse target separation between 0.1 micron and 50 microns.

50 55 In some implementations a method of fragmenting a tissue in an eye with a photodisruptive laser includes selecting a target region in the eye for fragmentation, and forming an array of cells in the target region by directing a beam of laser pulses to generate cell boundaries in the target region, with a cell size and laser parameters of the laser beam such that the tissue fragmentation requires a surgical time of less than two minutes, whereas a volumetric tissue fragmentation of the same target region with the same laser parameters would require a surgical time in excess of two minutes.

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In some implementations the laser parameters are at least one of a pulse duration between 0.01 and 50 picoseconds, a repetition rate between 10 kHz and 100 MHz, a pulse energy between 1 microJoule and 25 microJoule, and a pulse target separation between 0.1 micron and 50 microns, and the cell size is between 1 microns and 50 microns.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1a-c illustrate a volumetric eye disruption procedure.

FIG. 2 illustrates an aspiration step.

FIG. 3 illustrates an ophthalmic surgery system.

FIGS. 4a-b illustrate a regular cell array.

FIGS. 5a-d illustrate a layer-by-layer formation of a cell array.

FIGS. 6a-b illustrate a formation of a cell array on a cell-by-cell basis.

FIGS. 7a-c illustrate spherical and polyhedral cell structures.

DETAILED DESCRIPTION

This application describes examples and implementations of techniques and systems for laser surgery on the crystalline lens via photodisruption caused by laser pulses. Various lens surgical procedures for removal of the crystalline lens utilize various techniques to break up the lens into small fragments that can be removed from the eye through small incisions. These procedures may use manual mechanical instruments, ultrasound, heated fluids or lasers and tend to have significant drawbacks, including the need to enter the eye with probes in order to accomplish the fragmentation, and the limited precision associated with such lens fragmentation techniques. Photodisruptive laser technology can deliver laser pulses into the lens to optically fragment the lens without the insertion of a probe and thus can offer the potential for lens removal with improved control and efficiency. Laser-induced photodisruption has been widely used in laser ophthalmic surgery. In particular, Nd: YAG lasers have been frequently used as the laser sources, including lens fragmentation via laser induced photodisruption.

In a laser-induced lens fragmentation process, laser pulses interact with the lens tissue to generate gas in form of cavitation bubbles and decrease the lens tissue transparency. Because the laser pulses are sequentially delivered into the lens, the cavitation bubbles and reduced lens tissue transparency caused by the initial laser pulses can obscure the optical path of subsequent laser pulses and thus can interfere with the delivery of subsequent laser pulses directed to additional target positions in the lens by blocking, attenuating or scattering the subsequent laser pulses. This effect can reduce the actual optical power level of the subsequent laser pulses and thus adversely affect fragmentation at the deeper locations in the lens. Some known laser-induced lens fragmentation processes do not provide effective solutions to address this technical issue.

Based on effects of distinct regional properties of the lens and laser pulse parameters on spreading of gas produced during photodisruption, techniques, apparatus and systems described in this application can be used to effectively fragment the crystalline lens to remove a portion of or the entirety of the lens by using photodisruptive laser pulses with reduced interference caused by laser-induced air bubbles in the eye during the photodisruption process. The present methods and apparatus allow fragmentation of the entire or significant portions of the crystalline lens utilizing

a photodisruptive laser delivered with minimized interference from gas generated during photodisruption. In addition to reduced gas generation the method allows the use of significantly less total laser energy to treat the eye and reduces potential undesired effects such as heat generated by the laser and reduces overall procedure time. The removal of a portion of or the entirety of the crystalline lens can be achieved via aspiration with reduced or no need of other lens fragmentation or modification modalities.

The crystalline lens has multiple optical functions in the eye, including preservation of a transparent optical path and dynamic focusing capability. The lens is a unique tissue in the human body in that it continues to grow in size during gestation, after birth and throughout life. Since new lens fiber cells are added from a germinal center located on the equatorial periphery of the lens, the oldest lens fibers are located centrally in the lens. This region, called the lens nucleus, has been further subdivided into embryonal, fetal and adult nuclear zones. While the lens increases in diameter, it may also undergo compaction so that the properties of the nucleus are different from the cortex (Freel et al BMC Ophthalmology 2003, 3:1). In addition, since lens fiber cells undergo progressive loss of cytoplasmic elements and since there is no blood supply or lymphatics to supply the inner zone of the lens, it becomes progressively more difficult to preserve the optical clarity and other properties (e.g., lens flexibility) that serve the function of the lens. Of particular importance is the central core of the lens, occupying the inner approximately 6-8 mm in equatorial diameter and approximately 2-3.5 mm in axial diameter. This region has been shown to have reduced permeability to and from the metabolically active cortex and outer nucleus (Sweeney et al Exp Eye res, 1998;67, 587-95). A correlation with this observation is the progressive loss of transparency that is identified in the most common type of cataract in the same region in patients, as well as increases in lens stiffness that occur with age in a gradient fashion from the peripheral to central portion of the lens (Heys et al Molecular Vision 2004: 10:956-63). One result of such changes is the development of presbyopia and cataract that increase in severity and incidence with age.

The above identification of a central zone with different transport, optical and biomechanical properties has significant implications for fragmentation techniques with photodisruption, because one significant limitation to various laser-based lens fragmentation techniques is the uncontrolled spread of gas bubbles that can occur during photodisruption that can reduce the effectiveness of subsequent laser pulses in interacting with the lens. The layered structure of the lens body at different locations exhibits differing resistance to spread of cavitation bubble gas. Additionally, the softer peripheral layers can be sufficiently soft so as not to require photodisruption and/or significant fragmentation prior to aspiration and removal. These softer, less resistant peripheral layers however can allow the gas generated by photodisruption to spread and block subsequent laser pulses that are directed to fragment the harder central core. The precise determination of regions of a lens that are more or less resistant to the spread of cavitation bubble gas depends on individual characteristics of each patient including the age of the patient. The spread of gas can also be influenced by the particular laser parameters and treatment pattern applied to the target.

The tissue of the lens can be treated in an essentially uniform fashion. FIGS. 1a-c illustrate an example where a photodisruptive laser system is operated to place laser pulses essentially uniformly within a surgical region, e.g.,

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the eye lens, to be treated to allow aspiration and removal of the lens material. One way to fill the volume with laser is to direct the laser pulses with a scanner to form a bubble layer and fill the entire volume with a multitude of layers, as shown in FIG. 1c.

FIG. 2 illustrates that after the laser treatment, an aspiration device can be used to remove the disrupted lens material.

In such procedures, the laser pulse characteristics, such as their duration can range from 0.01 picoseconds (ps) to 50 picoseconds. The laser pulse energy, layer, line and spot separations can be optimized to achieve the highest effectiveness of breaking up the tissue while minimizing the effects of gas spreading, laser exposure and procedure time.

One determining factor of the laser pulse characteristics is the need to avoid or minimize a triggering of an uncontrolled gas spreading. Since the conditions and properties of the lenses can vary from patient to patient, the threshold laser pulse parameters to achieve this can vary as well. In some implementations, the laser energy per pulse can range from 1 microJoule (μJ) to 25 μJ and the spatial pulse separation between two initial pulses adjacent in space can fall within the range of 0.1 micron to 50 microns. The laser pulse duration can range from 0.01 picoseconds to 50 picoseconds and the laser repetition rate from 10 kHz to 100 MHz.

The parameters of the laser pulses and the scan pattern can be determined by various methods. For example, they can be based on a preoperative measurement of the lens optical or structural properties. The laser energy and the spot separation can also be selected based on a preoperative measurement of lens optical or structural properties and the use of an age-dependant algorithm. The pulsed laser is operated to direct a sequence of laser pulses to a target lens region of the lens to fragment the target lens region. The laser pulses may also be directed to one or more regions of the lens other than the target lens region, e.g., peripheral locations and/or the lens capsule, to create an opening or incision in the lens. After the desired fragmentation and incision are achieved, the laser pulses can be terminated and the fragmented target lens region and any other selected portions of the lens are removed from the lens body by aspiration.

The following sections describe techniques and laser systems for applying laser pulses to surfaces and boundaries of cells of predetermined size, shape and spatial distribution that differ from the above described uniform volumetric distribution of the laser pulses within the treated volume. Following such a laser treatment the lens tissue can subsequently break up along the surfaces and boundaries of the cells. The size of the cells or granules can be determined to be small enough that they can easily be removed by using e.g. an aspiration device. A typical aspiration device is a needle attached to a suction pump. For example a 23 gauge needle has an inner diameter of 0.34 mm. Cells smaller than the inner diameter of the aspiration needle can pass through the needle without clogging.

FIG. 3 illustrates a laser surgical system for performing such a non-uniform laser distribution process. An optics module 310 can focus and direct the laser beam to a target lens 301. The optics module 310 can include one or more lenses and may further include one or more reflectors. A control actuator can be included in the optics module 310 to adjust the focusing and the beam direction in response to a beam control signal. A system control module 320 can control both a pulsed laser 302 via a laser control signal and the optics module 310 via the beam control signal. An imaging device 330 may collect reflected or scattered light or sound from the target lens 301 to capture image data via

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the target lens 301. The captured image data can then be processed by the laser system control module 320 to determine the placement of the applied laser pulses. This control can be a dynamic alignment process during the surgical process to ensure that the laser beam is properly directed at each target position. The imaging device 330 can be implemented in various forms, including an optical coherent tomography (OCT) device. In other implementations, an ultrasound imaging device can also be used.

10 The system control module 320 may process image data from the imaging device 330 that includes the position offset information for the photodisruption byproducts in the target region. Based on the offset information obtained from the image data, the beam control signal can be generated to control the optics module 310, which can adjust the laser beam in response. A digital processing unit can be included in the system control module 320 to perform various data processing functions for the laser alignment and laser surgery. The digital processing unit can be programmed to 15 control the laser parameters of the initial laser pulses and the additional laser pulses, laser beam scanning direction from the posterior to anterior direction for the initial laser pulses and the laser movement of the additional laser pulses.

20 In one implementation, the pulsed laser 302 can be a high repetition rate pulsed laser at a pulse repetition rate of thousands of shots per second or higher with relatively low energy per pulse. Such a laser can be operated to use 25 relatively low energy per pulse to localize the tissue effect caused by laser-induced photodisruption. A form of this tissue effect is the formation of cavitation bubbles. In some 30 implementations, the impacted tissue region can have a size of the order of microns or tens of microns. This localized tissue effect can improve the precision of the laser surgery and can be desirable in certain ophthalmic surgical procedures. In one example of such surgery, placement of many hundred, thousands or millions of contiguous or near contiguous pulses, which may be separated by microns or tens of microns, can be used to achieve certain desired surgical 35 effect placement. Such procedures using high repetition rate pulsed lasers may require high precision in positioning each pulse in the target region during surgery, both regarding their absolute position with respect to a target location and their relative position with respect to preceding pulses. For example, in some cases, subsequent laser pulses may be required to be delivered next to each other with an accuracy of a few microns, when the time between pulses (the repetition rate) can be of the order of microseconds.

40 FIGS. 4a-b show an implementation of an ophthalmic surgical procedure, during which laser spots (or bubbles) are generated to form granules, the granules themselves forming a granule array. The laser spots can be generated to form a regular spatial pattern of the granules, as shown in FIG. 4b. Regularly spaced granules utilize the laser pulses well, since 45 they require a limited amount of laser energy to break up a target region. Nevertheless, in other implementations the granules may form an irregular or even random array.

45 The cells can be packed next to one another. Creating the side wall of one cell can simultaneously create the side of the neighboring cell as well, making the process efficient. The design of the individual cells and the cell pattern may be 50 selected based on the physical properties of the tissue to be treated. The bulk of the lens consists of concentric layers of elongated fiber cells. Cleavage of tissue parallel and perpendicular to the layers and individual fibers is different. Therefore, in some implementations a higher spot density 55 and/or laser pulse energy can be used to form cell boundaries which are perpendicular to layers and fibers.

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During the formation of a particular spatial pattern, different implementations of the present surgical method may utilize different scanning paths. A regular pattern can be built all at once or granule by granule. Which method to use may depend on the particular laser scanner and it is a matter of optimization to achieve higher precision and shorter procedure time.

In a particular implementation the granules, or cells, can be cubes. With an analogy to crystal cell structures, this pattern of cells can be described as a Simple Cubic (SC) crystal. Layers of these cubes can be formed simultaneously, followed by repeating the procedure in subsequent layers.

FIGS. 5a-d illustrate that in some implementations first a bubble layer can be generated with the laser pulses to form the bottom layer of the SC crystal, as shown in FIG. 5a. In some implementations, this bottom layer can be essentially transverse, or perpendicular, to an optical axis of the lens or the eye. As it is known, an optical axis can be defined in several different ways, with somewhat different outcomes. In what follows, the term "optical axis" will be used to refer to an axis defined by any one of these procedures, or even a compromise axis, defined as a direction falling between differently defined axes.

FIG. 5b illustrates that subsequent to the formation of the bottom layer, a regular array of cell walls can be generated. These walls can be essentially parallel to the optical axis, formed with a predetermined cell height.

FIGS. 5b and 5c illustrate that the scanner can raster, or sweep, first in one direction (FIG. 5b) then in an orthogonal direction (FIG. 5c).

FIG. 5d illustrates that a layer of cells can be completed by placing a bubble-layer to form the top of the cells. This "top" bubble-layer can then form the bottom bubble-layer for the next layer of cells. The target volume can be filled up with a regular array of granules/cell by repeating the steps 5a-d.

In some implementations, a smooth boundary layer can be formed around the regular array of cells in the surgical target region, partially, or in its entirety. Such a boundary layer can provide a smooth surface without the raggedness of the edges of the cell array.

In other implementations, the crystalline cell array/structure can be oriented differently, the bottom layer forming any angle with the optical axis of the eye. In yet other implementations, the layers themselves can be somewhat curved, to accommodate the natural curvature of the lens target region itself or the natural curvature of the focal plane of the surgical system. Such structures may not be entirely regular. They may contain deformations or lattice defects. These defects can be formed intentionally or may emerge during the creation of the cell array.

FIGS. 6a-b illustrate an alternative implementation, where complete cells of a layer can be formed individually one after the other by controlling the scanner to form all walls of a single cell, and to start forming the next cell only after the previous cell is completed.

FIG. 6a illustrates that rows of cells can be formed first to build a layer of cells.

FIG. 6b illustrates that subsequent layers can be formed on top of already created layers, to fill a surgical target volume.

The implementations which form the cells individually may have the following features.

First, FIGS. 7a-c illustrate that the shape of the cells can be different from the simplest shapes, like cubes. For example, the cell array can have a hexagonal base to form a Simple Hexagonal (SH) lattice. Or a target volume can be

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broken up into cells of a different type, such as spheres (FIG. 7a), separated by complementary small interstitial regions. Spherical cell shapes can minimize the occurrence of clogging in the aspiration needle. The type of the lattice, formed by the spherical cells can be selected to optimize the ratio of the volume of the spheres to the volume of the interstitial regions. These lattice types are known as "close packed" crystals structures. Face Centered Cubic (FCC) and Hexagonal Closest Packing (HCP) are two such structures.

In some implementations, the cells can have shapes which approximate spheres, such as polyhedral shapes. In these implementations, the polyhedral cells can form close packed structures, analogously to the lattice of spheres.

FIG. 7b illustrates a Truncated Rhombic Dodecahedron, which is an example of a polyhedron approximating a sphere.

FIG. 7c illustrates that truncated rhombic dodecahedrons can be close packed to form a layer, and fill a target volume with a stack of layers. When passing through the aspiration needle, these polyhedra can more readily roll than cubes and the likelihood of clogging is smaller.

Second, the laser scanner pattern can be optimized to speed up completion of the whole pattern. Creating individual cells with sizes of the order of 100 to 200 micrometers require small scanner displacements and can be performed at higher scanner speed. Larger scale moves of the scanner can be slower. The design of the scanner can be optimized effectively for achieving the shortest overall procedure time. Applying a combination of two different scanner types, a fast small displacement scanner and a slow but larger displacement scanner, can further optimize system performance. Building cells individually is also consistent with modular software design practices. A complete volumetric pattern can be created from building blocks; cells, rows and layers of cells and finally the complete pattern. An analogous approach can be effective in constructing a software code for the scanner drivers as well.

The above described or other patterns can be created by proceeding from the posterior to the anterior side of the lens or from the anterior to the posterior side. The former can be advantageous to avoid blocking the laser beam by bubbles previously formed in the target tissue. The latter may be preferable when a cataract is present in the lens and penetration of laser light through the cataract is already compromised. In that case fragmentation of the anterior portion of the lens may be necessary followed by aspiration of the treated portion and successive laser treatment and aspiration of the deeper-lying parts of the lens until the full volume is fragmented.

Additional features of implementations which fragment the target tissue in a granular or cellular form include the following.

1) Reduction of the amount of gas bubbles formed in the eye and thus reduction of the induced opacity of the tissue. Since a similar degree of tissue disruption can be achieved by considerably smaller number of bubbles in a granular/cellular procedure, this aspect can increase the effectiveness of the laser treatment to a substantial degree.

2) Reduction of the number of pulses applied to the tissue, which increases the speed of the procedure. Time is at a premium during eye surgery, as after about two minutes patients sometimes develop an increasing, hard-to-control eye movement. This can necessitate the abandonment of the surgical procedure. Therefore, if a new feature in a surgical procedure is capable of reducing a time of the surgery from above two minutes to below two minutes, that feature may increase the utility of the surgical procedure qualitatively.

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3) Reduction of the required total energy applied to the tissue, which reduces potential undesired side-effects related to the exposure of the eye to laser light. In most procedures, a substantial portion of the laser light passes through the surgical region and continues its way to the retina. The retina being a strongly light sensitive tissue itself, this transmitted surgical laser light may damage the retina to an undesirable or unacceptable degree. Thus, a reduction of the transmitted laser light can be an advantageous feature.

To quantitatively assess the different implementations, a comparison is provided for the amount of laser energy required for treating a given volume, and for the number of laser pulses required for volumetric and cellular fragmentation procedures.

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which can enter the tube at the least favored orientation, with its body diagonal perpendicular to the length of the tube, is about 196 micrometers. Actual implementations may use smaller grain sizes, such as 150 microns.

5 As Table 1 illustrates, methods based on forming cell-lattices can exhibit an increase of speed by a factor of 2.9 to 25.3 over the speed of the volumetric method as the size of the bubbles is varied. For a typical bubble size of 10 microns, the increase of speed can be about 5.4-fold. The speed ratio increases with decreasing bubble size. The improvement in the procedure time is approximately a factor of 10 for 5 micron bubble size and 25 for 2 micron bubble sizes. These are quite significant improvements over the volumetric method.

TABLE 1

Spot separation (um)	Cube size (um)	Number of pulses per mm ³ volumetric breakdown	Number of pulses per mm ³ granular breakdown	Ratio of pulses, volumetric vs. granular, ratio of procedure time
2	50	125000000	14400000	8.7
2	150	125000000	4933333	25.3
2	250	125000000	2976000	42.0
5	50	8000000	2160000	3.7
5	150	8000000	773333	10.3
5	250	8000000	470400	17.0
10	50	1000000	480000	2.1
10	150	1000000	186667	5.4
10	250	1000000	115200	8.7
20	50	125000	90000	1.4
20	150	125000	43333	2.9
20	250	125000	27600	4.5

Table 1 illustrates some results of the comparison, contrasting tissue breakdown by performing a volumetric method and by forming a Simple Cubic lattice of cells. Typically, the volume of an individual gas bubbles is approximately proportional to the energy of the femtosecond laser pulse which created the bubble. This proportionality holds for energies not too close to the threshold of producing plasma. Further, the individual pulses are directed such that the gas bubbles touch each other. In the volumetric method this translates to the spot, line, and layer separation being approximately equal to one another, all being set by the diameter of the bubbles. In the cellular implementation this translates to the cell boundaries being formed by touching spheres. It is noted that in practice, some overlap may be necessary for both volumetric and cell-array methods.

Table 1 reports comparison results, varying the spot separation from 2 microns to 20 microns and the cell size from 50 microns to 300 microns. The speed of the procedure was characterized by the number of pulses needed for a given total volume and the total energy needed.

In some implementations of the volumetric breakdown, the total energy needed to break down the tissue in the target region can be approximately independent of the size of the bubbles. This energy is of the order of 1 Joule per cubic millimeter of target volume. This relationship holds most accurately in the energy range in which the volume of an individual bubble is proportional to the laser pulse energy.

For implementations which form a lattice of cells, the speed and the corresponding energy depends both on the size of the individual bubbles and on the size of the cell. The speed increases with increasing cell sizes and decreasing bubble sizes. This is the result of the change in the volume to surface ratio of the cells as a function of their size. This comparison is based on using a 23 gauge needle which has inner diameter of 340 micrometers. The largest size cube

35 As mentioned above, the required total laser energy is proportional to the total volume of gas produced, which is proportional to the number of bubbles for bubbles of a fixed size. Therefore, among methods which use the same average laser power and create similarly sized bubbles, the procedure time is approximately proportional to the number of bubbles created. Thus, the speed improvement of the cell-array methods over the volumetric methods is proportional to the ratio R of the total number of pulses, as demonstrated in Table 1. Implementations with a different bubble size in general require different laser average power, repetition rate, and scanner speed setting. Nevertheless, it remains true for 40 implementations with all bubble sizes that granular/cellular fragmentation decreases the total energy and time required compared to volumetric fragmentation with the same bubble size. Thus

$$R = \frac{\text{Volume_of_gas_produced_in_volumetric_fragmentation}}{\text{Volume_of_gas_produced_in_granular_fragmentation}} \quad (1)$$

Also,

$$R = \frac{\text{Procedure_time_of_volumetric_fragmentation}}{\text{Procedure_time_of_granular_fragmentation}} \quad (2)$$

When the cell size is significantly larger than the bubble size, R can be approximately proportional to the Volume/Surface ratio of the cell. Since the volume of gas produced is approximately proportional to the product of the area of the cell boundaries multiplied with the bubble size, R is approximately proportional to a ratio of a cell size to a bubble size.

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$$R \propto \frac{\text{Cell_size}}{\text{Bubble_size}}.$$

Granular fragmentation with the smallest bubble size produces the smallest amount of gas in the target tissue and uses the smallest amount of total laser energy. In some implementations there can be a practical limit, how small a bubble size should be used. In some implementations the bubbles are closely packed, and the corresponding spot separation and line separation is nearly equal to the bubble size when creating the surface of a cell boundary. Although the laser parameters, average power, pulse energy and repetition rate can be chosen over a wide enough range to achieve the desired bubble size, spot and line separations, the scanning system can be limited in its speed and acceleration to generate a particular pattern. To keep the acceleration of the scanner under control at turning points, in some implementations the linear speed of progression of the bubble placement can be kept smaller than a limiting value, v_{lim} .

For a given granular pattern the total area of the cell boundaries, A, and as demonstrated in Table 1. the total number of pulses N per total volume are given for given bubble size. For example, for a close packed area $A=N*\text{bubble_size}^2$.

The total linear path of bubble placement s may equal $N*\text{bubble_size}$, which is also the speed of progression of bubble placement times the total procedure time, $s=v*T$. Therefore, in some approaches, the product $v*T*\text{bubble_size}$ may be approximately constant.

In order to minimize the total amount of gas produced and the total amount of laser energy used for a granular pattern, some approaches minimize the bubble size by selecting the linear speed of progression and the procedure time to their largest acceptable value v_{lim} , and T_{max} . Here T_{max} is the maximum procedure time tolerable by the clinical environment, less than 1 minute is acceptable, less than 30 seconds is desirable, dictated mainly by the tolerance of the patient to keep still during the procedure.

On the other hand, to minimize procedure time, the highest linear speed v_{lim} and the largest acceptable bubble size can be selected. The largest acceptable bubble size is determined by the amount of gas produced, pulse energy used, and by the required precision of the surgery.

Some implementations of the surgical system maximize the speed of scanner and lower the laser energy threshold for the formation of cavitation bubbles, in order to minimize bubble size. The surgeon has the choice to select particular parameters within the limitation of the surgical system to optimize the parameters for particular surgical outcomes. The decision may take into account the size of the surgically affected area, tissue parameters the age of the patient and other factors.

While this specification contains many specifics, these should not be construed as limitations on the scope of an invention or of what may be claimed, but, rather, as descriptions of features specific to particular embodiments of the invention. Certain features that are described in this specification in the context of separate embodiments can also be implemented in combination in a single embodiment. Conversely, various features that are described in the context of a single embodiment can also be implemented in multiple embodiments separately or in any suitable subcombination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as

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such, one or more features from a claimed combination can in some cases be excised from the combination, and the claimed combination may be directed to a subcombination or a variation of a subcombination.

5 The invention claimed is:

1. A method of fragmenting lens tissue of an eye with a laser surgical system, the method comprising:
generating a pulsed laser beam with a pulsed laser;
directing the laser beam with an optics module towards a target region in the lens tissue; and
controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries, wherein
the layers are created by scanning the pulsed laser with the optics module according to a curvature of the focal plane of the optics module to track the natural curvature of the lens.

2. The method of claim 1, the forming the regular array of cells comprising:

forming the cells with a size suitable for extraction by aspiration without additional lens fragmentation.

3. The method of claim 1, the forming the regular array of cells comprising:

forming the cells with a spatial extent less than 340 microns.

4. The method of claim 1, the forming the regular array of cells comprising:

controlling the optics module by the system control module to form the cells with a size such that a ratio of a number of bubbles created to form the regular array of cells in the target region to a number of bubbles created to photodisrupt the same target region with a volumetric method is greater than 1:1.4.

5. The method of claim 1, wherein:

walls of individual cells include photodisrupted bubbles other than corner bubbles of the cell, wherein the regular array of cells further comprises individual cells having walls that include photodisrupted bubbles to generate the cell boundaries.

6. The method of claim 1, wherein:

the regular array of cells includes a set of cells in a periodically repeating array.

7. A method of fragmenting lens tissue with a laser surgical system, the method comprising:

generating a pulsed laser beam with a pulsed laser;
directing the pulsed laser beam with an optics module towards a target region in the lens tissue; and

controlling the optics module by a system control module to form a regular array of cells in the target region by creating layers of photodisrupted bubbles to generate cell boundaries, wherein
a size of the cells is suitable for extraction by aspiration without additional lens fragmentation; and

walls of individual cells include photodisrupted bubbles other than corner bubbles of the cell, wherein the regular array of cells further comprises individual cells having walls that include photodisrupted bubbles to generate the cell boundaries.

8. The method of claim 7, the forming the regular array of cells comprising:

a spatial extent of the cells is less than 340 microns.

9. The method of claim 7, the forming the regular array of cells comprising:

controlling the optics module by the system control module to form the cells with a size such that a ratio of a number of bubbles created to form the regular array

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of cells in the target region to a number of bubbles created to photodisrupt the same target region with a volumetric method is greater than 1.4.

10. The method of claim 9, the forming the regular array of cells comprising:

controlling the optics module by the system control module to form the cells with a size such that a ratio of a number of bubbles created to form the regular array of cells in the target region to a number of bubbles created to photodisrupt the same target region with a 10 volumetric method is greater than 4.5.

11. The method of claim 7, the forming the regular array of cells comprising:

controlling the optics module by the system control module to form the cells with a size such that a ratio of 15 the cell size to a bubble size is greater than 4.5.

12. The method of claim 7, the forming the regular array of cells comprising:

controlling the optics module by the system control module to form the photodisrupted bubbles with a spot 20 separation of less than 20 microns.

13. The method of claim 7, the creating layers comprising:

controlling the optics module by the system control module to reduce a linear speed of progression of a bubble placement at turning points to be smaller than a 25 limiting value.

14. The method of claim 7, the creating layers comprising:

controlling the optics module by the system control module to form curved layers.

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